Suspend the Rules and Pass the Bill, HR. 6378, with An Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

115TH CONGRESS
2D SESSION

H. R. 6378

To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 16, 2018

Mrs. BROOKS of Indiana (for herself, Ms. ESHOO, Mr. WALDEN, and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, Veterans' Affairs, and Homeland Security, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

TITLE I—STRENGTHENING NATIONAL PREPAREDNESS AND RESPONSE FOR PUBLIC HEALTH EMERGENCIES

SEC. 101. COORDINATION OF PREPAREDNESS FOR AND RESPONSE TO ALL-HAZARDS PUBLIC HEALTH EMERGENCIES.

(a) IN GENERAL.—Section 2811 of the Public Health Service Act (42 U.S.C. 300hh–10) is amended—

(1) in subsection (b)—

(A) in paragraph (4)—

(i) in subparagraph (G)—

(I) by inserting ''the pandemic influenza and emerging infectious disease program established under section 319L(d), or'' before ''all-hazards medical and public health preparedness and response''; and

(II) by adding at the end (after and below clause (ii)) the following:

''Such drills and operations exercises shall be comprehensive, synchronized, and mutually supportive.''; and

(ii) by adding at the end the following new subparagraph:

''(I) THREAT AWARENESS.—Coordinate with the Director of the Centers for Disease Control and Prevention, the Director of National Intelligence, the Secretary of Homeland Security, the Assistant to the President for National Security Affairs, the Secretary of Defense, and other relevant Federal officials, such as the Secretary of Agriculture, to maintain a current assessment of national security threats and inform preparedness and response capabilities based on the range of the threats that have

the potential to result in a public health emergency.'';

(B) in paragraph (5), by adding at the end the following: ''Such logistical support shall include working with other relevant Federal, State, local, tribal, and territorial public health officials and private sector entities to identify the critical infrastructure assets, systems, and networks needed for the proper functioning of the health care and public health sectors that need to be maintained through any emergency or disaster, including entities capable of assisting with, responding to, and mitigating the effect of a public health emergency, including a public health emergency declared by the Secretary pursuant to section 319, or an emergency or major disaster declared by the President pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act or the National Emergencies Act, including by establishing methods to exchange critical information and deliver products consumed or used to preserve, protect, or sustain life, health, or safety, and sharing of specialized expertise.'';

(C) in paragraph (7)—

(i) in the matter preceding subparagraph (A)—

(I) by inserting ''the research and development activities of the pandemic influenza and emerging infectious disease program established under section 319L(d) with respect to qualified pandemic or epidemic products (as defined in section 319F–3), and'' before ''the medical countermeasure priorities described in subsection (d)''; and

(II) by striking ''Develop, and update not later than March 1 of each year'' and inserting ''Develop, by not later than September 30, 2019, and update not less than annually after the initial development,''; and

(ii) in each of subparagraphs (D) and (E), by striking ''not later than March 15 of each year'' and inserting in each such place ''not later than 14 days after each biennial development date''; and

(D) by adding at the end the following new paragraph:

''(8) REPORTING.—The Assistant Secretary for Preparedness and Response shall, beginning on the date of the enactment of this paragraph, submit to the Committee on Energy and Commerce of the House of Representatives weekly reports on the status and welfare of the children who, as a result of the 'zero tolerance' policy, were separated from their parent or guardian and are awaiting reunification with their parent or guardian, as well as the number of such children in facilities funded by the Department of Health and Human Services.'';

(2) in subsection (c), in the matter preceding paragraph (1), by striking ''shall'' and inserting ''shall, utilizing experience related to public health emergency preparedness and response, biodefense, medical countermeasures, and other relevant topics''; and

(3) in subsection (d)—

(A) in paragraph (1), by striking ''Not later than 180 days after the date of enactment of this subsection, and every year thereafter'' and inserting ''Not later than September 30, 2019, and every second year thereafter'';

(B) in paragraph (2)(C), by inserting after ''products'' the following: '', and ancillary med-

ical supplies to assist with the utilization of such products,''; and

(C) in paragraph (2)(J)(v), by striking ''the one-year period for which the report is submitted'' and inserting ''the two-year period for which the report is submitted''.

(b) COUNTERMEASURES BUDGET PLAN.—Section 2811(b)(7) of the Public Health Service Act (42 U.S.C. 300hh–10(b)(7)), as amended by subsection (a)(1)(C), is further amended—

(1) by striking subparagraph (A) and inserting the following:

''(A) include consideration of the entire medical countermeasures enterprise, including—

''(i) basic research and advanced research and development;

''(ii) approval, clearance, licensure, and authorized uses of products;

''(iii) procurement, stockpiling, maintenance, and potential replenishment (including manufacturing capabilities) of all products in the Strategic National Stockpile;

''(iv) the availability of technologies that may assist in the advanced research and development of countermeasures and opportunities to use such technologies to accelerate and navigate challenges unique to countermeasure research and development;

''(v) development of clinical guidance for use of medical countermeasures; and

''(vi) postmarket evaluation of the safety and efficacy of medical countermeasures used pursuant to an emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act.'';

(2) by redesignating subparagraphs (D) and (E) as subparagraphs (E) and (F), respectively; and

(3) by inserting after subparagraph (C) the following:

''(D) identify the full range of anticipated medical countermeasure needs related to research and development, procurement, and stockpiling, including the potential need for indications, dosing, and administration technologies, and other countermeasure needs as applicable and appropriate;''.

SEC. 102. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

Subtitle B of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh–10 et seq.) is amended—

(1) by redesignating section 2811A as 2811B; and

(2) by inserting after section 2811 the following:

"SEC. 2811A. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE.

''(a) IN GENERAL.—The Secretary shall establish and the Assistant Secretary for Preparedness and Response shall convene an interagency panel of advisors to be known as the Public Health Emergency Medical Countermeasures Enterprise (in this section referred to as the 'PHEMCE').

''(b) MEMBERS.—In addition to the Assistant Secretary for Preparedness and Response, who shall serve as chair, the PHEMCE shall include the following members:

''(1) The Director of the Biomedical Advanced Research and Development Authority (or the Director's designee).

''(2) The Director of the Centers for Disease Control and Prevention (or the Director's designee).

''(3) The Director of the National Institutes of Health (or the Director's designee).

''(4) The Commissioner of Food and Drugs (or the Commissioner's designee).

''(5) The Secretary of Defense (or the Secretary's designee).

''(6) The Secretary of Homeland Security (or the Secretary's designee).

''(7) The Secretary of Agriculture (or the Secretary's designee).

''(8) The Secretary of Veterans Affairs (or the Secretary's designee).

''(9) The Secretary of State (or the Secretary's designee).

''(10) The Director of National Intelligence (or the Director's designee).

''(11) The Director of the Central Intelligence Agency (or the Director's designee).

''(12) Representatives of any other Federal agencies, as the Assistant Secretary for Preparedness and Response determines appropriate.

''(c) FUNCTIONS.—The PHEMCE shall—

''(1) advise the Assistant Secretary for Preparedness and Response regarding research, development, and procurement of security countermeasures (as defined in section 319F–2(c)) based on the health security needs of the United States; and

''(2) assist the Assistant Secretary for Preparedness and Response in the identification of gaps in public health preparedness and response related to such security countermeasures and challenges to addressing such needs (including any regulatory challenges).''.

SEC. 103. NATIONAL HEALTH SECURITY STRATEGY.

Section 2802 of the Public Health Service Act (42 U.S.C. 300hh–1) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking ''2014'' and inserting ''2018''; and

(ii) by striking the second sentence and inserting the following: ''Such National Health Security Strategy shall describe potential emergency health security threats and identify the process for achieving the preparedness goals described in subsection (b) to be prepared to identify and respond to such threats and shall be consistent with the national preparedness goal (as described in section 504(a)(19) of the Homeland Security Act of 2002), the National Incident Management System (as

defined in section 501(7) of such Act), and the National Response Plan developed pursuant to section 504 of such Act, or any successor plan.'';

(B) in paragraph (2), by inserting before the period at the end of the second sentence the following: '', and an analysis of any changes to the evidence-based benchmarks and objective standards under sections 319C–1 and 319C–2''; and

(C) in paragraph (3)—

(i) by striking ''2009'' and inserting ''2022'';

(ii) by inserting ''(including gaps in the environmental health and animal health workforces, as applicable), describing the status of such workforce'' after ''gaps in such workforce'';

(iii) by striking ''and identifying strategies'' and inserting ''identifying strategies''; and

(iv) by inserting before the period at the end '', and identifying current capabilities to meet the requirements of section 2803''; and

(2) in subsection (b)—

(A) in paragraph (2)—

(i) in subparagraph (A), by striking ''and investigation'' and inserting ''investigation, and related information technology activities'';

(ii) in subparagraph (B), by striking ''and decontamination'' and inserting ''decontamination, relevant health care services and supplies, and transportation and disposal of medical waste''; and

(iii) by adding at the end the following:

''(E) Response to environmental hazards.'';

(B) in paragraph (3)—

(i) in the matter preceding subparagraph (A), by striking ''including mental health'' and inserting ''including pharmacies, mental health facilities,'';

(ii) in subparagraph (F), by inserting ''or exposures to agents that could cause a public health emergency'' before the period; and

(iii) by amending subparagraph (G) to read as follows:

''(G) Optimizing a coordinated and flexible approach to the emergency response and medical surge capacity of hospitals, other health care facilities, critical care, trauma care (which may include trauma centers), and emergency medical systems, which may include the implementation of guidelines for regional health care emergency preparedness and response systems under section 319C–3.'';

(C) in paragraph (5), by inserting ''and other applicable compacts'' after ''Compact''; and

(D) by adding at the end the following:

''(9) ZOONOTIC DISEASE, FOOD, AND AGRICULTURE.—Improving coordination among Federal, State, local, tribal, and territorial entities (including through consultation with the Secretary of Agriculture) to prevent, detect, and respond to outbreaks of plant or animal disease (including zoonotic disease) that could compromise national security resulting from a deliberate attack, a naturally occurring threat, the intentional adulteration of food, or other public health threats, taking into account interactions between animal health, human health, and animals' and humans' shared environment as di-

rectly related to public health emergency preparedness and response capabilities, as applicable.

''(10) GLOBAL HEALTH SECURITY.—Assessing current or potential health security threats from abroad to inform domestic public health preparedness and response capabilities.''.

SEC. 104. IMPROVING EMERGENCY PREPAREDNESS AND RESPONSE CONSIDERATIONS FOR CHILDREN.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319D the following:

''SEC. 319D–1. CHILDREN'S PREPAREDNESS UNIT.

''(a) ENHANCING EMERGENCY PREPAREDNESS FOR CHILDREN.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention (referred to in this subsection as the 'Director'), shall maintain an internal team of experts, to be known as the Children's Preparedness Unit (referred to in this subsection as the 'Unit'), to work collaboratively to provide guidance on the considerations for, and the specific needs of, children before, during, and after public health emergencies. The Unit shall inform the Director regarding emergency preparedness and response efforts pertaining to children at the Centers for Disease Control and Prevention.

''(b) EXPERTISE.—The team described in subsection (a) shall include one or more pediatricians, which may be a developmental-behavioral pediatrician, and may also include behavioral scientists, child psychologists, epidemiologists, biostatisticians, health communications staff, and individuals with other areas of expertise, as the Secretary determines appropriate.

''(c) DUTIES.—The team described in subsection (a) may—

''(1) assist State, local, tribal, and territorial emergency planning and response activities related to children, which may include developing, identifying, and sharing best practices;

''(2) provide technical assistance, training, and consultation to Federal, State, local, tribal, and territorial public health officials to improve preparedness and response capabilities with respect to the needs of children, including providing such technical assistance, training, and consultation to eligible entities in order to support the achievement of measurable evidence-based benchmarks and objective standards applicable to sections 319C–1 and 319C–2;

''(3) improve the utilization of methods to incorporate the needs of children in planning for and

responding to a public health emergency, including public awareness of such methods;

''(4) coordinate with, and improve, public-private partnerships, such as health care coalitions pursuant to sections 319C–2 and 319C–3, to address gaps and inefficiencies in emergency preparedness and response efforts for children;

''(5) provide expertise and input during the development of guidance and clinical recommendations to address the needs of children when preparing for, and responding to, public health emergencies, including pursuant to section 319C–3; and

''(6) carry out other duties related to preparedness and response activities for children, as the Secretary determines appropriate.''.

SEC. 105. REAUTHORIZING THE NATIONAL ADVISORY COMMITTEE ON CHILDREN AND DISASTERS.

Section 2811B of the Public Health Service Act, as redesignated by section 102(1), is amended—

(1) in subsection (b)(2), by inserting '', mental and behavioral,'' after ''medical'';

(2) in subsection (d)—

(A) in paragraph (1), by striking ''15'' and inserting ''25''; and

(B) by striking paragraph (2) and inserting the following:

''(2) REQUIRED NON-FEDERAL MEMBERS.—The Secretary, in consultation with such other heads of Federal agencies as may be appropriate, shall appoint to the Advisory Committee under paragraph (1) at least 13 individuals to perform the duties described in subsections (b) and (c), including—

''(A) at least 2 non-Federal professionals with expertise in pediatric medical disaster planning, preparedness, response, or recovery;

''(B) at least 2 representatives from State, local, tribal, or territorial agencies with expertise in pediatric disaster planning, preparedness, response, or recovery;

''(C) at least 4 members representing health care professionals, which may include members with expertise in pediatric emergency medicine; pediatric trauma, critical care, or surgery; the treatment of pediatric patients affected by chemical, biological, radiological, or nuclear agents and emerging infectious diseases; pediatric mental or behavioral health related to children affected by a public health emergency; or pediatric primary care; and

''(D) other members as the Secretary determines appropriate, of whom—

''(i) at least one such member shall represent a children's hospital;

''(ii) at least one such member shall be an individual with expertise in schools or child care settings;

''(iii) at least one such member shall be an individual with expertise in children and youth with special health care needs; and

''(iv) at least one such member shall be an individual with expertise in the needs of parents or family caregivers, including the parents or caregivers of children with disabilities.

''(3) FEDERAL MEMBERS.—The Advisory Committee under paragraph (1) shall include the following Federal members or their designees:

''(A) The Assistant Secretary for Preparedness and Response.

''(B) The Director of the Biomedical Advanced Research and Development Authority.

''(C) The Director of the Centers for Disease Control and Prevention.

''(D) The Commissioner of Food and Drugs.

''(E) The Director of the National Institutes of Health.

''(F) The Assistant Secretary of the Administration for Children and Families.

''(G) The Administrator of the Health Resources and Services Administration.

''(H) The Administrator of the Federal Emergency Management Agency.

''(I) The Administrator of the Administration for Community Living.

''(J) The Secretary of Education.

''(K) Representatives from such Federal agencies (such as the Substance Abuse and Mental Health Services Administration and the Department of Homeland Security) as the Secretary determines appropriate to fulfill the duties of the Advisory Committee under subsections (b) and (c).

''(4) TERM OF APPOINTMENT.—Each member of the Advisory Committee appointed under paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the Advisory Committee appointees serving on the date of

enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, or appointees who are initially appointed after such date of enactment, in order to provide for a staggered term of appointment for all members.

''(5) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member appointed under paragraph (2) may serve not more than 3 terms on the Advisory Committee, and not more than 2 of which may be served consecutively.'';

(3) in subsection (e), by adding at the end ''At least one meeting per year shall be an in-person meeting.'';

(4) by redesignating subsection (f) as subsection (g);

(5) by inserting after subsection (e) the following:

''(f) COORDINATION.—The Secretary shall coordinate activities authorized under this section and section 2811C, in accordance with section 2811C(d).''; and

(6) in subsection (g), as so redesignated, by striking ''2018'' and inserting ''2023''.

SEC. 106. NATIONAL DISASTER MEDICAL SYSTEM.

(a) PURPOSE OF SYSTEM.—Clause (ii) of section 2812(a)(3)(A) of the Public Health Service Act (42 U.S.C. 300hh–11(a)(3)(A)) is amended to read as follows:

> ''(ii) be present at locations, and for limited periods of time, specified by the Secretary on the basis that the Secretary has determined that a location is at risk of a public health emergency during the time specified, or there is a significant potential for a public health emergency.''.

(b) REVIEW OF THE NATIONAL DISASTER MEDICAL SYSTEM.—Section 2812(b)(2) of the Public Health Service Act (42 U.S.C. 300hh–11(b)(2)) is amended to read as follows:

> ''(2) JOINT REVIEW AND MEDICAL SURGE CAPACITY STRATEGIC PLAN.—
>
> ''(A) REVIEW.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary, in coordination with the Secretary of Homeland Security, the Secretary of Defense, and the Secretary of Veterans Affairs, shall conduct a joint review of the National Disaster Medical System. Such review shall include—

''(i) an evaluation of medical surge capacity, as described in section 2803(a);

''(ii) an assessment of the available workforce of the intermittent disaster-response personnel described in subsection (c);

''(iii) the capacity of the workforce described in clause (ii) to respond to all hazards, including capacity to simultaneously respond to multiple public health emergencies and to respond to a nationwide public health emergency;

''(iv) the effectiveness of efforts to recruit, retain, and train such workforce; and

''(v) gaps that may exist in such workforce and recommendations for addressing such gaps.

''(B) UPDATES.—As part of the National Health Security Strategy under section 2802, the Secretary shall update the findings from the review under subparagraph (A) and provide recommendations to modify the policies of the National Disaster Medical System as necessary.''.

(c) DIRECT HIRE AUTHORITY.—Section 2812(c)(1) of the Public Health Service Act (42 U.S.C. 300hh–

11(c)(1)) is amended by inserting ''(or, for the period beginning on the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 and ending on September 30, 2021, without regard to those provisions of title 5, United States Code, governing appointments in the competitive service)'' after ''in accordance with applicable civil service laws and regulations''.

(d) SERVICE BENEFIT; NOTIFICATION OF SHORTAGE.—Section 2812(c) of the Public Health Service Act (42 U.S.C. 300hh–11(c)) is amended by adding at the end the following:

''(3) SERVICE BENEFIT.—Individuals appointed to serve under this subsection shall be considered public safety officers under part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968. The Secretary shall provide notification to eligible individuals of any effect such designation may have on other benefits for which such individuals are eligible, including benefits from private entities.

''(4) NOTIFICATION.—Not later than 30 days after the date on which the Secretary determines the number of intermittent disaster-response personnel of the National Disaster Medical System is insufficient to address a public health emergency or poten-

tial public health emergency, the Secretary shall submit to the congressional committees of jurisdiction a notification detailing—

''(A) the impact such shortage could have on meeting public health needs and emergency medical personnel needs during a public health emergency; and

''(B) any identified measures to address such shortage.''.

(e) AUTHORIZATION OF APPROPRIATIONS.—Section 2812(g) of the Public Health Service Act (42 U.S.C. 300hh–11(g)) is amended by striking ''$52,700,000 for each of fiscal years 2014 through 2018'' and inserting ''$57,400,000 for each of fiscal years 2019 through 2023''.

SEC. 107. VOLUNTEER MEDICAL RESERVE CORPS.

Section 2813 of the Public Health Service Act (42 U.S.C. 300hh–15)) is amended—

(1) in subsection (a), by amending the second sentence to read as follows: ''The Secretary may appoint a Director to head the Corps and oversee the activities of the Corps chapters that exist at the State, local, and tribal levels.''; and

(2) in subsection (i), by striking ''$11,200,000 for each of fiscal years 2014 through 2018'' and in-

serting ''$6,000,000 for each of fiscal years 2019 through 2023''.

SEC. 108. CONTINUING THE ROLE OF THE DEPARTMENT OF VETERANS AFFAIRS.

Section 8117(g) of title 38, United States Code, is amended by striking ''$155,300,000 for each of fiscal years 2014 through 2018'' and inserting ''$126,800,000 for each of fiscal years 2019 through 2023''.

SEC. 109. AUTHORIZING THE NATIONAL ADVISORY COMMITTEE ON SENIORS AND DISASTERS.

Subtitle B of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh et seq.), as amended by section 102, is further amended by inserting after section 2811B the following:

''SEC. 2811C. NATIONAL ADVISORY COMMITTEE ON SENIORS AND DISASTERS.

''(a) ESTABLISHMENT.—The Secretary, in consultation with the Secretary of Homeland Security and the Secretary of Veterans Affairs, shall establish an advisory committee to be known as the National Advisory Committee on Seniors and Disasters (referred to in this section as the 'Advisory Committee').

''(b) DUTIES.—

''(1) IN GENERAL.—The Advisory Committee shall—

''(A) provide advice and consultation with respect to the activities carried out pursuant to section 2814, as applicable and appropriate;

''(B) evaluate and provide input with respect to the medical and public health needs of seniors related to the preparation for, response to, and recovery from all-hazards emergencies; and

''(C) provide advice and consultation with respect to State emergency preparedness and response activities and seniors, including related drills and exercises pursuant to the preparedness goals under section 2802(b).

''(2) ADDITIONAL DUTIES.—The Advisory Committee may provide advice and recommendations to the Secretary with respect to seniors and the medical and public health grants and cooperative agreements as applicable to preparedness and response activities under this title and title III.

''(3) MEMBERSHIP.—

''(A) IN GENERAL.—The Secretary, in consultation with such other heads of agencies as appropriate, shall appoint not more than 25 members to the Advisory Committee. In appointing such members, the Secretary shall en-

sure that the total membership of the Advisory Committee is an odd number.

''(B) REQUIRED MEMBERS.—The members appointed under paragraph (1) shall include—

''(i) the Assistant Secretary for Preparedness and Response;

''(ii) the Director of the Biomedical Advanced Research and Development Authority;

''(iii) the Director of the Centers for Disease Control and Prevention;

''(iv) the Commissioner of Food and Drugs;

''(v) the Director of the National Institutes of Health;

''(vi) the Administrator of the Centers for Medicare & Medicaid Services;

''(vii) the Administrator of the Administration for Community Living;

''(viii) the Administrator of the Federal Emergency Management Agency;

''(ix) the Under Secretary for Health of the Department of Veterans Affairs;

''(x) at least 2 non-Federal health care professionals with expertise in geri-

atric medical disaster planning, preparedness, response, or recovery;

''(xi) at least 2 representatives of State, local, territorial, or tribal agencies with expertise in geriatric disaster planning, preparedness, response, or recovery; and

''(xii) representatives of such other Federal agencies (such as the Department of Energy and the Department of Homeland Security) as the Secretary determines necessary to fulfill the duties of the Advisory Committee.

''(c) MEETINGS.—The Advisory Committee shall meet not less frequently than biannually.

''(d) ADVISORY COMMITTEE COORDINATION.—

''(1) IN GENERAL.—The Secretary shall coordinate activities authorized under this section and sections 2811B and 2811D, and make efforts to reduce unnecessary or duplication of meetings, recommendations, and reporting under such sections. Members of the advisory committees under this section and sections 2811B and 2811D, or their designees, shall meet periodically, and not less than annually, to—

''(A) review the recommendations developed by such committees to coordinate, as appropriate, the implementation of recommendations, in order to reduce gaps, overlap, and duplication of effort in Federal programs or by Federal grantees; and

''(B) align preparedness and response programs or activities to address the overlapping needs of children, individuals with disabilities, and seniors and any challenges in preparing for and responding to such needs.

''(2) NOTIFICATION.—The Secretary shall notify the congressional committees of jurisdiction upon the convening of each meeting under paragraph (1), and provide minutes from such meeting not later than 90 days after the meeting.

''(e) SUNSET.—The Advisory Committee shall terminate on September 30, 2023.''.

SEC. 110. NATIONAL ADVISORY COMMITTEE ON INDIVIDUALS WITH DISABILITIES AND DISASTERS.

Subtitle B of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh et seq.), as amended by sections 102 and 109, is further amended by inserting after section 2811C the following:

"SEC. 2811D. NATIONAL ADVISORY COMMITTEE ON INDIVIDUALS WITH DISABILITIES AND DISASTERS.

"(a) ESTABLISHMENT.—Not later than 90 days after the date of this section, the Secretary shall establish a national advisory committee to be known as the National Advisory Committee on Individuals with Disabilities in All-Hazards Emergencies (referred to in this section as the 'Advisory Committee').

"(b) DUTIES.—The Advisory Committee shall—

"(1) provide advice and consultation with respect to activities carried out pursuant to section 2814, as applicable and appropriate;

"(2) evaluate and provide input with respect to the public health, accessibility, and medical needs of individuals with disabilities as they relate to preparation for, response to, and recovery from public health emergencies; and

"(3) provide advice and consultation with respect to State emergency preparedness and response activities, including related drills and exercises pursuant to the preparedness goals under section 2802(b).

"(c) REPORT.—Not later than February 1, 2020, the Advisory Committee shall submit to the Secretary, the Committee on Energy and Commerce of the House of

Representatives, the Committee on Homeland Security of the House of Representatives, the Committee on Veterans' Affairs of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Veterans Affairs of the Senate, and the Committee on Homeland Security and Governmental Affairs of the Senate a report that evaluates the extent to which individuals with disabilities are thoroughly included in disaster preparedness planning and disaster recovery. Such report shall—

''(1) include recommendations that offer specific improvements that could be made across local, State, tribal, territorial, and Federal efforts to improve outcomes in areas that include—

''(A) preparedness;

''(B) planning;

''(C) exercises and drills;

''(D) alerts, warning, and notifications;

''(E) evacuation;

''(F) sheltering;

''(G) accessing emergency programs and services;

''(H) medical care (including mental health care);

''(I) temporary housing;

''(J) mitigation; and

''(K) community resilience; and

''(2) assess the strength of existing policies to incorporate such individuals as well as the efficacy of implementation.

''(d) COMPOSITION.—

''(1) IN GENERAL.—The Secretary, in consultation with such other heads of agencies and departments as may be appropriate, shall appoint not to exceed 25 members to the Advisory Committee.

''(2) REQUIRED MEMBERS.—In carrying out paragraph (1), the Secretary shall appoint to the Advisory Committee such individuals as may be appropriate to perform the duties described in subsection (b), which shall include—

''(A) the Assistant Secretary for Preparedness and Response (or their designee);

''(B) the Director of the Administration for Community Living (or their designee);

''(C) the Director of the Biomedical Advanced Research and Development Authority (or their designee);

''(D) the Director of the Centers for Disease Control and Prevention (or their designee);

''(E) the Commissioner of Food and Drugs (or their designee);

''(F) the Director of the National Institutes of Health (or their designee);

''(G) the Administrator of the Federal Emergency Management Agency (or their designee);

''(H) the Director of Office of Disability Integration and Coordination (or their designee);

''(I) the Officer for Civil Rights and Civil Liberties of the Department of Homeland Security (or their designee);

''(J) the Chair of the National Council on Disability (or their designee);

''(K) the Chair of the United States Access Board (or their designee);

''(L) the Director of the Disability Rights Section of the Department of Justice (or their designee);

''(M) the Secretary of the Department of Education (or their designee);

''(N) the Secretary of the Department of Transportation (or their designee);

''(O) the Secretary of the Department of Housing and Urban Development (or their designee);

''(P) a representative from the Department of Veterans Affairs Health Administration's Office of Emergency Management;

''(Q) the Director of the Bureau of Prisons (or their designee);

''(R) at least four representatives who are individuals with disabilities that have substantive expertise in disability inclusive emergency management policy and operations;

''(S) at least two non-Federal health care professionals with expertise in disability accessibility before, during, and after disasters, medical and mass care disaster planning, preparedness, response, or recovery; and

''(T) at least two representatives from State, local, territorial, or tribal agencies with expertise in disability-inclusive disaster planning, preparedness, response, or recovery.

''(e) MEETINGS.—The Advisory Committee shall meet not less than biannually.

''(f) DISABILITY DEFINED.—For purposes of this section, the term 'disability' has the meaning given such

term in section 3 of the Americans with Disabilities Act of 1990.

''(g) TERMINATION OF COMMITTEE.—

''(1) IN GENERAL.—The Advisory Committee shall terminate on September 30, 2023.

''(2) RECOMMENDATION.—Not later than March 30, 2023, the Secretary shall submit to Congress a recommendation on whether the Advisory Committee should be extended.''.

SEC. 111. CONSIDERATION FOR AT-RISK INDIVIDUALS.

(a) AT-RISK INDIVIDUALS IN THE NATIONAL HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B) of the Public Health Service Act (42 U.S.C. 300hh–1(b)(4)(B)) is amended by striking ''this section and sections 319C–1, 319F, and 319L'' and inserting ''this Act''.

(b) COUNTERMEASURE CONSIDERATIONS.—Section 319L(c)(6) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(6)) is amended—

(1) by striking ''elderly'' and inserting ''senior citizens''; and

(2) by inserting ''with relevant characteristics that warrant consideration during the process of researching and developing such countermeasures and products'' before the period at the end.

SEC. 112. PUBLIC HEALTH SURVEILLANCE.

(a) GOAL.—Section 2802(b) of the Public Health Service Act (42 U.S.C. 300hh–1(b)), as amended by sections 103 and 111, is further amended by adding at the end the following:

''(11) PUBLIC HEALTH SURVEILLANCE.—Strengthening the ability of State, tribal, territorial, and local health departments to adapt and expand existing public health surveillance infrastructure to develop a robust national surveillance capacity to capture data on the impact of emerging public health threats. Such capacity shall include emerging threats to pregnant and postpartum women and infants, including through monitoring birth defects, developmental disabilities, and other short-term and long-term adverse outcomes.''.

(b) ASSURANCE OF CONFIDENTIALITY.—Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) is amended—

(1) by striking ''or 307'' and inserting ''307, or 2802(b)(11)''; and

(2) by striking ''or 306'' and inserting ''306, or 2802(b)(11)''.

SEC. 113. GAO STUDY AND REPORT ON DISASTER MEDICAL ASSISTANCE TEAMS.

(a) STUDY AND REPORT.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the mission readiness of disaster medical assistance teams with respect to current and emerging natural and man-made threats.

(2) COMPONENTS.—The study conducted pursuant to paragraph (1) shall include an assessment, in relation to disaster medical assistance teams, of—

(A) whether the mission readiness of such teams, and the needs relating to such readiness, have changed over time;

(B) the standards the Assistant Secretary for Preparedness and Response of the Department of Health and Human Services uses to determine—

(i) the training needs of such teams; and

(ii) whether such teams are mission ready;

(C) how to improve the determinations described in subparagraph (B);

(D) the extent to which the provision of additional resources (including personnel, training, and equipment) has addressed mission readiness concerns; and

(E) the extent to which the Assistant Secretary has developed plans to address mission readiness issues.

(3) REPORT.—Not later than one year after the date of enactment of this Act, the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—

(A) the findings of the study conducted pursuant to paragraph (1); and

(B) related recommendations.

(b) DISASTER MEDICAL ASSISTANCE TEAM DEFINED.—In this section, the term ''disaster medical assistance team'' means a disaster medical assistance team operating pursuant to the National Disaster Medical System established under section 2812 of the Public Health Service Act (42 U.S.C. 300hh–11).

SEC. 114. MILITARY AND CIVILIAN PARTNERSHIP FOR TRAUMA READINESS GRANT PROGRAM.

Title XII of the Public Health Service Act (42 U.S.C. 300d et seq.) is amended by adding at the end the following new part:

"PART I—MILITARY AND CIVILIAN PARTNERSHIP FOR TRAUMA READINESS GRANT PROGRAM

"SEC. 1291. MILITARY AND CIVILIAN PARTNERSHIP FOR TRAUMA READINESS GRANT PROGRAM.

''(a) MILITARY TRAUMA TEAM PLACEMENT PROGRAM.—

''(1) IN GENERAL.—The Secretary shall award grants to not more than 20 eligible high-acuity trauma centers to enable military trauma teams to provide, on a full-time basis, trauma care and related acute care at such trauma centers.

''(2) LIMITATIONS.—In the case of a grant awarded under paragraph (1) to an eligible high-acuity trauma center, such grant—

''(A) shall be for a period of at least 3 years and not more than 5 years (and may be renewed at the end of such period); and

''(B) shall be in an amount that does not exceed $1,000,000 per year.

''(3) AVAILABILITY OF FUNDS AFTER PERFORMANCE PERIOD.—Notwithstanding section 1552 of title 31, United States Code, or any other provision of law, funds available to the Secretary for obligation for a grant under this subsection shall remain available for expenditure for 100 days after the last day of the performance period of such grant.

''(b) MILITARY TRAUMA CARE PROVIDER PLACEMENT PROGRAM.—

''(1) IN GENERAL.—The Secretary shall award grants to eligible trauma centers to enable military trauma care providers to provide trauma care and related acute care at such trauma centers.

''(2) LIMITATIONS.—In the case of a grant awarded under paragraph (1) to an eligible trauma center, such grant—

''(A) shall be for a period of at least 1 year and not more than 3 years (and may be renewed at the end of such period); and

''(B) shall be in an amount that does not exceed, in a year—

''(i) $100,000 for each military trauma care provider that is a physician at such eligible trauma center; and

''(ii) $50,000 for each other military trauma care provider at such eligible trauma center.

''(c) GRANT REQUIREMENTS.—

''(1) DEPLOYMENT.—As a condition of receipt of a grant under this section, a grant recipient shall agree to allow military trauma care providers providing care pursuant to such grant to be deployed by

the Secretary of Defense for military operations, for training, or for response to a mass casualty incident or public health emergency.

''(2) USE OF FUNDS.—Grants awarded under this section to an eligible trauma center may be used to train and incorporate military trauma care providers into such trauma center, including expenditures for malpractice insurance, office space, information technology, specialty education and supervision, trauma programs, research, and State license fees for such military trauma care providers.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the extent to which State licensing requirements for health care professionals are preempted by other Federal law from applying to military trauma care providers.

''(e) REPORTING REQUIREMENTS.—

''(1) REPORT TO THE SECRETARY AND THE SECRETARY OF DEFENSE.—Each eligible trauma center or eligible high-acuity trauma center awarded a grant under subsection (a) or (b) for a year shall submit to the Secretary and the Secretary of Defense a report for such year that includes information on—

''(A) the number and types of trauma cases managed by military trauma teams or military trauma care providers pursuant to such grant during such year;

''(B) the financial impact of such grant on the trauma center;

''(C) the educational impact on resident trainees in centers where military trauma teams are assigned;

''(D) any research conducted during such year supported by such grant; and

''(E) any other information required by the Secretaries for the purpose of evaluating the effect of such grant.

''(2) REPORT TO CONGRESS.—Not less than once every 2 years, the Secretary, in consultation with the Secretary of Defense, shall submit a report to Congress that includes information on the effect of placing military trauma care providers in trauma centers awarded grants under this section on—

''(A) maintaining readiness of military trauma care providers for battlefield injuries;

''(B) providing health care to civilian trauma patients in both urban and rural settings;

''(C) the capability to respond to surges in trauma cases, including as a result of a large scale event; and

''(D) the financial state of the trauma centers.

''(f) DEFINITIONS.—For purposes of this part:

''(1) ELIGIBLE TRAUMA CENTER.—The term 'eligible trauma center' means a Level I, II, or III trauma center that satisfies each of the following:

''(A) Such trauma center has an agreement with the Secretary of Defense to enable military trauma care providers to provide trauma care and related acute care at such trauma center.

''(B) Such trauma center utilizes a risk-adjusted benchmarking system to measure performance and outcomes, such as the Trauma Quality Improvement Program of the American College of Surgeons.

''(C) Such trauma center demonstrates a need for integrated military trauma care providers to maintain or improve the trauma clinical capability of such trauma center.

''(2) ELIGIBLE HIGH-ACUITY TRAUMA CENTER.—The term 'eligible high-acuity trauma center'

means a Level I trauma center that satisfies each of the following:

''(A) Such trauma center has an agreement with the Secretary of Defense to enable military trauma teams to provide trauma care and related acute care at such trauma center.

''(B) At least 20 percent of patients of such trauma center in the most recent 3-month period for which data is available are treated for a major trauma at such trauma center.

''(C) Such trauma center utilizes a risk-adjusted benchmarking system to measure performance and outcomes, such as the Trauma Quality Improvement Program of the American College of Surgeons.

''(D) Such trauma center is an academic training center—

''(i) affiliated with a medical school;

''(ii) that maintains residency programs and fellowships in critical trauma specialties and subspecialties, and provides education and supervision of military trauma team members according to those specialties and subspecialties; and

''(iii) that undertakes research in the prevention and treatment of traumatic injury.

''(E) Such trauma center serves as a disaster response leader for its community, such as by participating in a partnership for State and regional hospital preparedness established under section 319C–2.

''(3) MAJOR TRAUMA.—The term 'major trauma' means an injury that is greater than or equal to 15 on the injury severity score.

''(4) MILITARY TRAUMA TEAM.—The term 'military trauma team' means a complete military trauma team consisting of military trauma care providers.

''(5) MILITARY TRAUMA CARE PROVIDER.—The term 'military trauma care provider' means a member of the Armed Forces who furnishes emergency, critical care, and other trauma acute care, including a physician, military surgeon, physician assistant, nurse, respiratory therapist, flight paramedic, combat medic, or enlisted medical technician.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section,

$15,000,000 for each of fiscal years 2019 through 2023, of which—

''(1) $10,000,000 shall be for carrying out subsection (a); and

''(2) $5,000,000 shall be for carrying out subsection (b).''.

SEC. 115. IMPROVEMENT OF LOAN REPAYMENT PROGRAM FOR PREVENTION ACTIVITIES.

Section 317F of the Public Health Service Act (42 U.S.C. Sec. 247b–7) is amended—

(1) in subsection (a)(1)—

(A) by inserting after ''conduct prevention activities'' the following: '', including rapid response to major health threats,''; and

(B) by striking ''$35,000'' and inserting ''$50,000'';

(2) in subsection (a)(2)(B), by striking ''3 years'' and inserting ''2 years''; and

(3) in subsection (c), by striking ''$500,000'' and all that follows through the period at the end and inserting ''$1,000,000 for each of the fiscal years 2019 through 2023.''.

SEC. 116. REPORT ON ADEQUATE NATIONAL BLOOD SUPPLY.

Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report containing recommendations related to maintaining an adequate national blood supply, including challenges associated with continuous recruitment of blood donors, ensuring adequacy of blood supply in the case of public health emergencies, and implementation of safety measures and innovation.

SEC. 117. GRANTS TO STUDY AND REDUCE HEALTH CARE ACQUIRED INFECTIONS.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following new section:

"SEC. 399V–7. GRANTS TO STUDY AND REDUCE HEALTH CARE ACQUIRED INFECTIONS.

''(a) IN GENERAL.—The Secretary shall award grants to eligible entities to study and reduce health care acquired infections that occur in hospital settings.

''(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a), an entity shall be a health care system that has—

''(1) extensive experience in—

''(A) treating patients to full recovery from a high-consequence pathogen such as Ebola; and

''(B) teaching and training health care professionals in a health care setting; and

''(2) a plan to assess, not later than three years after the date on which the entity receives such a grant, how such grant impacts how health care professionals are trained and evaluated.

''(c) USE OF FUNDS.—Grants awarded under this section to an eligible entity shall be used—

''(1) to conduct evidence-based health care research on reducing the transmission of health care acquired infections that occur in hospital settings, specifically targeting interprofessional providers, including nurses, physicians, laboratorians, environmental services, food services, facilities, and health care administration; and

''(2) to support the four strategic goals of the Department of Health and Human Services relating to—

''(A) strengthening health care;

''(B) advancing scientific knowledge and innovation;

"(C) advancing the health, safety, and well-being of the people of the United States; and

"(D) ensuring efficiency, transparency, accountability, and effectiveness of programs.

"(d) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2019 through 2023.".

TITLE II—OPTIMIZING STATE AND LOCAL ALL-HAZARDS PREPAREDNESS AND RESPONSE

SEC. 201. PUBLIC HEALTH EMERGENCIES.

(a) RESPONSE FUND.—Section 319 of the Public Health Service Act (42 U.S.C. 247d) is amended—

(1) in subsection (b)—

(A) in paragraph (1)—

(i) in the first sentence, by inserting before the period the following: ", or if the Secretary determines there is the significant potential for a public health emergency, to allow the Secretary to rapidly respond to the immediate needs resulting

from such public health emergency or potential public health emergency''; and

(ii) by inserting after the first sentence the following: ''The Secretary shall plan for the expedited distribution of amounts in the Fund to appropriate agencies and entities.'';

(B) by redesignating paragraph (2) as paragraph (3);

(C) by inserting after paragraph (1) the following:

''(2) USES.—The Secretary may use amounts in the Fund established under paragraph (1)—

''(A) to facilitate coordination between and among Federal, State, local, tribal, and territorial entities and public and private health care entities that the Secretary determines may be affected by a public health emergency or potential public health emergency referred to in paragraph (1) (including communication of such entities with relevant international entities, as applicable);

''(B) to make grants, provide for awards, enter into contracts, and conduct supportive investigations pertaining to such a public health

emergency or potential public health emergency, including further supporting programs under sections 319C–1 and 319C–2;

"(C) to facilitate and accelerate, as applicable, advanced research and development of security countermeasures (as defined in section 319F–2), qualified countermeasures (as defined in section 319F–1), or qualified pandemic or epidemic products (as defined in section 319F–3), that are applicable to such a public health emergency or potential public health emergency;

"(D) to strengthen biosurveillance capabilities and laboratory capacity to identify, collect, and analyze information regarding such a public health emergency or potential public health emergency, including the systems under section 319D;

"(E) to support initial emergency operations and assets related to preparation and deployment of intermittent disaster-response personnel under section 2812, and the Medical Reserve Corps under section 2813; and

"(F) to carry out other activities, as the Secretary determines applicable and appropriate."; and

(D) by inserting after paragraph (3), as so redesignated, the following:

''(4) REVIEW.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary, in coordination with the Assistant Secretary for Preparedness and Response, shall conduct a review of the Fund under this subsection, and provide recommendations to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives on policies to improve such Fund for the uses described in paragraph (2).

''(5) GAO REVIEW AND REPORT.—The Comptroller General of the United States shall conduct a review of the Fund under this subsection, including the uses and the resources available in the Fund. Not later than 4 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and

Pensions of the Senate a report on such review, including recommendations related to such review.''; and

(2) in subsection (c), by striking ''section.'' and inserting ''section or funds otherwise provided for emergency response.''.

(b) TEMPORARY REASSIGNMENT OF FEDERALLY FUNDED PERSONNEL.—Section 319(e)(8) of the Public Health Service Act (42 U.S.C. 247d(e)(8)) is amended by striking ''2018'' and inserting ''2023''.

SEC. 202. IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.

(a) IN GENERAL.—Section 319C–1 of the Public Health Service Act (42 U.S.C. 247d–3a) is amended—

(1) in subsection (a), by inserting '', acting through the Director of the Centers for Disease Control and Prevention,'' after ''the Secretary'';

(2) in subsection (b)(2)(A)—

(A) in clause (vi), by inserting '', including public health agencies with specific expertise that may be relevant to public health security, such as environmental health agencies,'' after ''stakeholders'';

(B) in clause (viii), by striking at the end ''and'';

(C) in clause (ix), by adding at the end ''and''; and

(D) by inserting after clause (ix) the following new clause:

''(x) a description of—

''(I) the measures the entity will have in place to prioritize nursing facilities and skilled nursing facilities with respect to public health emergency preparedness in the same manner as such plan will prioritize hospitals, while ensuring that, in prioritizing nursing facilities, skilled nursing facilities, and hospitals, the entity will retain the discretion to prioritize among such facilities; and

''(II) the plans that utility companies within the entity's jurisdiction have in place to ensure that utilities will remain functioning or return to functioning as soon as practicable during outages caused by natural or manmade disasters;'';

(3) in subsection (e), by striking '', and local emergency plans.'' and inserting '', local emergency

plans, and any regional health care emergency preparedness and response system established pursuant to the applicable guidelines under section 319C–3.''; and

(4) in subsection (h)(1)(A), by striking ''$641,900,000 for fiscal year 2014 for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5)), and $641,900,000 for each of fiscal years 2015 through 2018'' and inserting ''$670,000,000 for each of fiscal years 2019 through 2023''.

(b) EXCEPTION RELATING TO APPLICATION OF CERTAIN REQUIREMENTS.—Section 319C–1(g) of the Public Health Service Act (42 U.S.C. 247d–3a(g)) is amended—

(1) in paragraph (5)—

(A) by striking ''Beginning with fiscal year 2009'' and inserting ''Beginning with fiscal year 2019'';

(B) by striking ''for the immediately preceding fiscal year'' and inserting ''for either of the two immediately preceding fiscal years''; and

(C) by striking ''2008'' and inserting ''2019''; and

(2) by amending subparagraph (A) of paragraph (6) to read as follows:

''(A) IN GENERAL.—The amounts described in this paragraph are the following amounts that are payable to an entity for activities described in section 319C–1 or 319C–2:

''(i) For each of the first two fiscal years immediately following a fiscal year in which an entity experienced a failure described in subparagraph (A) or (B) of paragraph (5) by the entity, an amount equal to 10 percent of the amount the entity was eligible to receive for each such fiscal year.

''(ii) For each of the first two fiscal years immediately following two consecutive fiscal years in which an entity experienced such a failure, an amount equal to 15 percent of the amount the entity was eligible to receive for each of such first two fiscal years, disregarding any withholding of funds that would have been made in each such year by virtue of clause (i). The amount determined pursuant to the previous sentence shall be in lieu of any

amount that would have been withheld for each such year by virtue of clause (i).

''(iii) For each of the first two fiscal years immediately following three consecutive fiscal years in which an entity experienced such a failure, an amount equal to 20 percent of the amount the entity was eligible to receive for each of such first two fiscal years, disregarding any withholding of funds that would have been made in each such year by virtue of clauses (i) and (ii). The amount determined pursuant to the previous sentence shall be in lieu of any amount that would have been withheld for each such year by virtue of clauses (i) and (ii).

''(iv) For each of the first two fiscal years immediately following four consecutive fiscal years in which an entity experienced such a failure, an amount equal to 25 percent of the amount the entity was eligible to receive for each of such first two fiscal years, disregarding any withholding of funds that would have been made in each such year by virtue of clauses (i), (ii),

and (iii). The amount determined pursuant to the previous sentence shall be in lieu of any amount that would have been withheld for each such year by virtue of clauses (i), (ii), and (iii).''.

(c) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on the date of enactment of this Act and apply with respect to cooperative agreements awarded on or after such date of enactment.

SEC. 203. STRENGTHENING THE HOSPITAL PREPAREDNESS PROGRAM.

Section 319C–2 of the Public Health Service Act (42 U.S.C. 247d–3b) is amended—

(1) by amending the section heading to read as follows: ''**STATE AND REGIONAL HEALTH CARE PREPAREDNESS AND RESPONSE TO IMPROVE SURGE CAPACITY**'';

(2) in subsection (a), by striking ''hospital preparedness for'' and inserting ''health care preparedness for and response to'';

(3) in subsection (b)(1)(A)—

(A) in the matter preceding clause (i)—

(i) by striking ''partnership'' and inserting ''coalition''; and

(ii) by striking ''consisting of'' and inserting ''that includes'';

(B) in clause (ii), by striking ''and'' at the end;

(C) in clause (iii)(III), by striking ''and'' at the end; and

(D) by adding at the end the following:

''(iv) an emergency medical service organization; and

''(v) an emergency management organization; and'';

(4) in subsection (c), by inserting after ''preparedness'' the following: ''and response'';

(5) in subsection (d)—

(A) in paragraph (1)(A)—

(i) in clause (i), by striking ''; and'' and inserting a semicolon;

(ii) by redesignating clause (ii) as clause (iii); and

(iii) by inserting after clause (i) the following:

''(ii) among one or more facilities in a regional health care emergency system under section 319C–3; and'';

(B) in paragraph (1)(B), by striking ''partnership'' each place it appears and inserting ''coalition''; and

(C) in paragraph (2)(C), by striking ''medical preparedness'' and inserting ''preparedness and response'';

(6) in subsection (f), by striking ''partnership'' and inserting ''coalition'';

(7) in subsection (g)(2)—

(A) by striking ''Partnerships'' and inserting ''Coalitions'';

(B) by striking ''partnerships'' and inserting ''coalitions''; and

(C) by inserting after ''preparedness'' the following: ''and response'';

(8) in subsection (i)(1)—

(A) by striking ''An entity'' and inserting ''A coalition'';

(B) by striking ''such partnership'' and inserting ''such coalition''; and

(C) by adding at the end the following: ''In submitting reports pursuant to this paragraph, an entity shall include information on the progress (if any) that the entity has made towards the implementation of section 319C–3.'';

(9) in subsection (j)(1), by striking ''$374,700,000 for each of fiscal years 2014 through 2018'' and inserting ''$264,600,000 for each of fiscal years 2019 through 2023''; and

(10) in subsection (j)(2), in the paragraph heading, by striking ''PARTNERSHIPS'' and inserting ''COALITIONS''.

SEC. 204. IMPROVING BENCHMARKS AND STANDARDS FOR PREPAREDNESS AND RESPONSE.

(a) EVALUATING MEASURABLE EVIDENCE-BASED BENCHMARKS AND OBJECTIVE STANDARDS.—Section 319C–1 of the Public Health Service Act (42 U.S.C. 247d–3a) is amended by inserting after subsection (j) the following:

''(k) EVALUATION.—

''(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 and every 2 years thereafter, the Secretary shall conduct an evaluation of the evidence-based benchmarks and objective standards required under subsection (g). Such evaluation shall be submitted to the congressional committees of jurisdiction together with the National Health Security

Strategy under section 2802, at such time as such strategy is submitted.

''(2) CONTENT.—The evaluation under this paragraph shall include—

''(A) a review of evidence-based benchmarks and objective standards, and associated metrics and targets;

''(B) a discussion of changes to any evidence-based benchmarks and objective standards, and the effect of such changes on the ability to track whether entities are meeting or making progress toward the goals under this section and, to the extent practicable, the applicable goals of the National Health Security Strategy under section 2802;

''(C) a description of amounts received by eligible entities, as described in subsection (b) and section 319C–2(b), and amounts received by subrecipients and the effect of such funding on meeting evidence-based benchmarks and objective standards; and

''(D) recommendations, as applicable and appropriate, to improve evidence-based benchmarks and objective standards to more accurately assess the ability of entities receiving

awards under this section to better achieve the goals under this section and section 2802.''.

(b) EVALUATING THE PARTNERSHIP FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS.—Section 319C–2(i)(1) (42 U.S.C. 247–3b(i)(1)), as amended by section 203, is further amended by striking ''section 319C–1(g), (i), and (j)'' and inserting ''section 319C–1(g), (i), (j), and (k)''.

SEC. 205. PUBLIC HEALTH AND HEALTH CARE SYSTEM SITUATIONAL AWARENESS AND BIOSURVEILLANCE CAPABILITIES.

(a) FACILITIES, CAPACITIES, AND BIOSURVEILLANCE CAPABILITIES.—Section 319D of the Public Health Service Act (42 U.S.C. 247d–4) is amended—

(1) in the section heading, by striking ''**REVITALIZING**'' and inserting ''**FACILITIES AND CAPACITIES OF**'';

(2) in subsection (a)—

(A) in the subsection heading, by striking ''FACILITIES; CAPACITIES'' and inserting ''IN GENERAL'';

(B) in paragraph (1), by striking ''and improved'' and inserting '', improved, and appropriately maintained'';

(C) in paragraph (3), in the matter preceding subparagraph (A), by striking ''expand, enhance, and improve'' and inserting ''expand, improve, enhance, and appropriately maintain''; and

(D) by adding at the end the following:

''(4) STUDY OF RESOURCES FOR FACILITIES AND CAPACITIES.—Not later than June 1, 2022, the Comptroller General of the United States shall conduct a study on Federal spending in fiscal years 2013 through 2018 for activities authorized under this subsection. Such study shall include a review and assessment of obligations and expenditures directly related to each activity under paragraphs (2) and (3), including a specific accounting of, and delineation between, obligations and expenditures incurred for the construction, renovation, equipping, and security upgrades of facilities and associated contracts under this subsection, and the obligations and expenditures incurred to establish and improve the situational awareness and biosurveillance network under subsection (b), and shall identify the agency or agencies incurring such obligations and expenditures.'';

(3) in subsection (b)—

(A) in the subsection heading, by striking ''NATIONAL'' and inserting ''ESTABLISHMENT OF SYSTEMS OF PUBLIC HEALTH '';

(B) in paragraph (1)(B), by inserting ''immunization information systems,'' after ''centers,''; and

(C) in paragraph (2)—

(i) by inserting ''develop a plan to, and'' after ''The Secretary shall''; and

(ii) by inserting ''and in a form readily usable for analytical approaches'' after ''in a secure manner''; and

(D) by amending paragraph (3) to read as follows:

''(3) STANDARDS.—

''(A) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary, in cooperation with health care providers, State, local, tribal, and territorial public health officials, and relevant Federal agencies (including the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology),

shall, as necessary, adopt technical and reporting standards, including standards for interoperability as defined by section 3000, for networks under paragraph (1) and update such standards as necessary. Such standards shall be made available on the internet website of the Department of Health and Human Services, in a manner that does not compromise national security.

''(B) DEFERENCE TO STANDARDS DEVELOPMENT ORGANIZATIONS.—In adopting and implementing standards under this subsection and subsection (c), the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards entities.'';

(4) in subsection (c)—

(A) in paragraph (1)—

(i) by striking ''Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Secretary'' and inserting ''The Secretary'';

(ii) by inserting ", and improve as applicable and appropriate," after "shall establish";

(iii) by striking "of rapid" and inserting "of, rapid"; and

(iv) by striking "such connectivity" and inserting "such interoperability";

(B) by amending paragraph (2) to read as follows:

"(2) COORDINATION AND CONSULTATION.—In establishing and improving the network under paragraph (1) the Secretary shall—

"(A) facilitate coordination among agencies within the Department of Health and Human Services that provide, or have the potential to provide, information and data to, and analyses for, the situational awareness and biosurveillance network under paragraph (1), including coordination among relevant agencies related to health care services, the facilitation of health information exchange (including the Office of the National Coordinator for Health Information Technology), and public health emergency preparedness and response; and

''(B) consult with the Secretary of Agriculture, the Secretary of Commerce (and the Director of the National Institute of Standards and Technology), the Secretary of Defense, the Secretary of Homeland Security, and the Secretary of Veterans Affairs, and the heads of other Federal agencies, as the Secretary determines appropriate.'';

(C) in paragraph (3)—

(i) by redesignating subparagraphs (A) through (E) as clauses (i) through (v), respectively, and adjusting the margins accordingly;

(ii) in clause (iv), as so redesignated—

(I) by inserting ''immunization information systems,'' after ''poison control,''; and

(II) by striking '' and clinical laboratories'' and inserting '', clinical laboratories, and public environmental health agencies'';

(iii) by striking ''The network'' and inserting the following:

''(A) IN GENERAL.—The network''; and

(iv) by adding at the end the following:

''(B) REVIEW.—Not later than 2 years after the date of the enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 and every 6 years thereafter, the Secretary shall conduct a review of the elements described in subparagraph (A). Such review shall include a discussion of the addition of any elements pursuant to clause (v), including elements added to advancing new technologies, and identify any challenges in the incorporation of elements under subparagraph (A). The Secretary shall provide such review to the congressional committees of jurisdiction.'';

(D) in paragraph (5)—

(i) by redesignating subparagraphs (A) through (D) as clauses (i) through (iv), respectively, and adjusting the margins accordingly;

(ii) by striking ''In establishing'' and inserting the following:

''(A) IN GENERAL.—In establishing'';

(iii) by adding at the end the following:

''(B) PUBLIC MEETING.—

''(i) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary shall convene a public meeting for purposes of discussing and providing input on the potential goals, functions, and uses of the network described in paragraph (1) and incorporating the elements described in paragraph (3)(A).

''(ii) EXPERTS.—The public meeting shall include representatives of relevant Federal agencies (including representatives from the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology); State, local, tribal, and territorial public health officials; stakeholders with expertise in biosurveillance and situational awareness; stakeholders with expertise in capabilities relevant to

biosurveillance and situational awareness, such as experts in informatics and data analytics (including experts in prediction, modeling, or forecasting); and other representatives as the Secretary determines appropriate.

''(iii) TOPICS.—Such public meeting shall include a discussion of—

''(I) data elements, including minimal or essential data elements, that are voluntarily provided for such network, which may include elements from public health and public and private health care entities, to the extent practicable;

''(II) standards and implementation specifications that may improve the collection, analysis, and interpretation of data during a public health emergency;

''(III) strategies to encourage the access, exchange, and use of information;

''(IV) considerations for State, local, tribal, and territorial capabilities

and infrastructure related to data exchange and interoperability;

''(V) privacy and security protections provided at the Federal, State, local, tribal, and territorial levels, and by nongovernmental stakeholders; and

''(VI) opportunities for the incorporation of innovative technologies to improve the network.''; and

(iv) in subparagraph (A), as so designated by clause (ii)—

(I) in clause (i), as so redesignated—

(aa) by striking ''as determined'' and inserting ''as adopted''; and

(bb) by inserting ''and the National Institute of Standards and Technology'' after ''Office of the National Coordinator for Health Information Technology'';

(II) in clause (iii), as so redesignated, by striking ''; and'' and inserting a semicolon;

(III) in clause (iv), as so redesignated, by striking the period and inserting ''; and''; and

(IV) by adding at the end the following:

''(v) pilot test standards and implementation specifications, consistent with the process described in section 3002(b)(3)(C), which State, local, tribal, and territorial public health entities may utilize, on a voluntary basis, as a part of the network.'';

(E) by redesignating paragraph (6) as paragraph (7);

(F) by inserting after paragraph (5) the following:

''(6) STRATEGY AND IMPLEMENTATION PLAN.—

''(A) IN GENERAL.—Not later than 18 months after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Secretary shall submit to the congressional committees of jurisdiction a coordinated strategy and an accompanying implementation plan that—

''(i) is informed by the public meeting under paragraph (5)(B);

''(ii) includes a review and assessment of existing capabilities of the network and related infrastructure, including input provided by the public meeting under paragraph (5)(B);

''(iii) identifies and demonstrates the measurable steps the Secretary will carry out to—

''(I) develop, implement, and evaluate the network described in paragraph (1), utilizing elements described in paragraph (3)(A);

''(II) modernize and enhance biosurveillance activities, including strategies to include innovative technologies and analytical approaches (including prediction and forecasting for pandemics and all-hazards) from public and private entities;

''(III) improve information sharing, coordination, and communication among disparate biosurveillance systems supported by the Department of

Health and Human Services, including the identification of methods to improve accountability, better utilize resources and workforce capabilities, and incorporate innovative technologies within and across agencies; and

''(IV) test and evaluate capabilities of the interoperable network of systems to improve situational awareness and biosurveillance capabilities;

''(iv) includes performance measures and the metrics by which performance measures will be assessed with respect to the measurable steps under clause (iii); and

''(v) establishes dates by which each measurable step under clause (iii) will be implemented.''.

''(B) ANNUAL BUDGET PLAN.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 and on an annual basis thereafter, in accordance with the strategy and implementation plan under this

paragraph, the Secretary shall, taking into account recommendations provided by the National Biodefense Science Board, develop a budget plan based on the strategy and implementation plan under this section. Such budget plan shall include—

''(i) a summary of resources previously expended to establish, improve, and utilize the nationwide public health situational awareness and biosurveillance network under paragraph (1);

''(ii) estimates of costs and resources needed to establish and improve the network under paragraph (1) according to the strategy and implementation plan under subparagraph (A);

''(iii) the identification of gaps and inefficiencies in nationwide public health situational awareness and biosurveillance capabilities, resources, and authorities needed to address such gaps; and

''(iv) a strategy to minimize and address such gaps and improve inefficiencies.'';

(G) in paragraph (7), as so redesignated—

(i) in subparagraph (A), by inserting ''(taking into account zoonotic disease, including gaps in scientific understanding of the interactions between human, animal, and environmental health)'' after ''human health'';

(ii) in subparagraph (B)—

(I) by inserting ''and gaps in surveillance programs'' after ''surveillance programs''; and

(II) by striking ''; and'' and inserting a semicolon;

(iii) in subparagraph (C)—

(I) by inserting '', animal health organizations related to zoonotic disease,'' after ''health care entities''; and

(II) by striking the period and inserting ''; and''; and

(iv) by adding at the end the following:

''(D) provide recommendations to the Secretary on policies and procedures to complete the steps described in this paragraph in a manner that is consistent with section 2802.''; and

(H) by adding at the end the following:

''(8) SITUATIONAL AWARENESS AND BIOSURVEILLANCE AS A NATIONAL SECURITY PRIORITY.—The Secretary, on a periodic basis as applicable and appropriate, shall meet with the Director of National Intelligence to inform the development and capabilities of the nationwide public health situational awareness and biosurveillance network.'';

(5) in subsection (d)—

(A) in paragraph (1)—

(i) by inserting ''environmental health agencies,'' after ''public health agencies,''; and

(ii) by inserting ''immunization programs,'' after ''poison control centers,''; and

(B) in paragraph (2)—

(i) in subparagraph (B), by striking ''and'' at the end;

(ii) in subparagraph (C), by striking the period and inserting ''; and''; and

(iii) by adding after subparagraph (C) the following:

''(D) an implementation plan that may include measurable steps to achieve the purposes described in paragraph (1).''; and

(C) by striking paragraph (5) and inserting the following:

''(5) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to States, localities, tribes, and territories or a consortium of States, localities, tribes, and territories receiving an award under this subsection regarding interoperability and the technical standards set forth by the Secretary.'';

(6) by redesignating subsections (f) and (g) as subsections (i) and (j), respectively; and

(7) by inserting after subsection (e) the following:

''(f) PERSONNEL AUTHORITIES.—

''(1) SPECIALLY QUALIFIED PERSONNEL.—In addition to any other personnel authorities, to carry out subsection (b) and subsection (c), the Secretary may—

''(A) appoint highly qualified individuals to scientific or professional positions at the Centers for Disease Control and Prevention, not to exceed 30 such employees at any time (specific to positions authorized by this subsection), with

expertise in capabilities relevant to biosurveillance and situational awareness, such as experts in informatics and data analytics (including experts in prediction, modeling, or forecasting), and other related scientific or technical fields; and

''(B) compensate individuals appointed under subparagraph (A) in the same manner and subject to the same terms and conditions in which individuals appointed under 9903 of title 5, United States Code, are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of that title relating to classification and General Schedule pay rates.

''(2) LIMITATIONS.—The Secretary shall exercise the authority under paragraph (1) in a manner that is consistent with the limitations described in section 319F–1(e)(2).

''(g) TIMELINE.—The Secretary shall accomplish the purposes under subsections (b) and (c) no later than September 30, 2023, and shall provide a justification to the congressional committees of jurisdiction for any missed or delayed implementation of measurable steps identified under subsection (c)(6)(A)(iii).

''(h) INDEPENDENT EVALUATION.—Not later than 3 years after the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the Secretary and the congressional committees of jurisdiction a report concerning the activities conducted under subsections (b) and (c), and provide recommendations, as applicable and appropriate, on necessary improvements to the biosurveillance and situational awareness network.''.

(b) AUTHORIZATION OF APPROPRIATIONS.—Subsection (i) of section 319D of the Public Health Service Act (42 U.S.C. 247d–4), as redesignated by subsection (a)(6), is amended by striking ''$138,300,000 for each of fiscal years 2014 through 2018'' and inserting ''$161,800,000 for each of fiscal years 2019 through 2023''.

SEC. 206. AUTHORIZATION OF APPROPRIATIONS FOR EMERGENCY SYSTEM FOR ADVANCED REGISTRATION OF VOLUNTEER HEALTH PROFESSIONALS.

Section 319I(k) of the Public Health Service Act (42 U.S.C. 247d–7b(k)) is amended by striking ''fiscal years 2014 through 2018'' and inserting ''fiscal years 2019 through 2023''.

SEC. 207. REGIONAL HEALTH CARE EMERGENCY PREPAREDNESS AND RESPONSE SYSTEMS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319C–2 the following new section:

"SEC. 319C–3. GUIDELINES FOR REGIONAL HEALTH CARE EMERGENCY PREPAREDNESS AND RESPONSE SYSTEMS.

''(a) PURPOSE.—It is the purpose of this section to identify and provide guidelines for regional systems of hospitals, health care facilities, and other public and private sector entities, with varying levels of capability to treat patients and increase medical surge capacity during, in advance of, and immediately following a public health emergency, including threats posed by one or more chemical, biological, radiological, and nuclear agents, including emerging infectious diseases.

''(b) GUIDELINES.—The Assistant Secretary for Preparedness and Response, in consultation with the Director of the Centers for Disease Control and Prevention, the Administrator of the Centers for Medicare & Medicaid Services, the Administrator of the Health Resources and Services Administration, the Commissioner of Food and Drugs, the Assistant Secretary for Mental Health and Substance Use, the Assistant Secretary of Labor for Occupational Safety and Health, the Secretary of Veterans Af-

fairs, the heads of such other Federal agencies as the Secretary determines to be appropriate, and State, local, tribal, and territorial public health officials, shall, not later than 2 years after the date of enactment of this section—

''(1) identify and develop a set of guidelines relating to practices and protocols for all-hazards public health emergency preparedness and response for hospitals and health care facilities to provide appropriate patient care during, in advance of, or immediately following, a public health emergency, resulting from one or more chemical, biological, radiological, or nuclear agents, including emerging infectious diseases (which may include existing practices, such as trauma care and medical surge capacity and capabilities), with respect to—

''(A) a regional approach to identifying hospitals and health care facilities based on varying capabilities and capacity to treat patients affected by such emergency, including—

''(i) the manner in which the system will coordinate with and integrate the health care coalitions and entities described in section 319C–2(b); and

''(ii) informing and educating appropriate first responders and health care sup-

ply chain partners of the regional emergency preparedness and response capabilities and medical surge capacity of such hospitals and health care facilities in the community;

''(B) physical and technological infrastructure, laboratory capacity, staffing, blood supply, and other supply chain needs, taking into account resiliency, geographic considerations, and rural considerations;

''(C) protocols or best practices for the safety and personal protection of workers who handle human remains and health care workers (including with respect to protective equipment and supplies, waste management processes, and decontamination), sharing of specialized experience among the health care workforce, behavioral health, psychological resilience, and training of the workforce, as applicable;

''(D) in a manner that allows for disease containment (within the meaning of section 2802(b)(2)(B)), coordinated medical triage, treatment, and transportation of patients, based on patient medical need (including patients in rural areas), to the appropriate hospitals or

health care facilities within the regional system or, as applicable and appropriate, between systems in different States or regions; and

''(E) the needs of children and other at-risk individuals;

''(2) make such guidelines available on the public website of the Department of Health and Human Services in a manner that does not compromise national security; and

''(3) update such guidelines as appropriate, including based on input received pursuant to subsections (c) and (f), to address new and emerging public health threats.

''(c) CONSIDERATIONS.—In identifying, developing, and updating guidelines under subsection (b), the Assistant Secretary for Preparedness and Response shall—

''(1) include input from hospitals and health care facilities (including health care coalitions under section 319C–2), State, local, tribal, and territorial public health departments, and health care or subject matter experts (including experts with relevant expertise in chemical, biological, radiological, or nuclear threats, and emerging infectious disease), as the Assistant Secretary determines appropriate, to meet the goals under section 2802(b)(3);

''(2) consult and engage with appropriate health care providers and professionals, including physicians, nurses, first responders, health care facilities (including hospitals, primary care clinics, community health centers, mental health facilities, ambulatory care facilities, and dental health facilities), pharmacies, emergency medical providers, trauma care providers, environmental health agencies, public health laboratories, poison control centers, blood banks, and other experts that the Assistant Secretary determines appropriate, to meet the goals under section 2802(b)(3);

''(3) consider feedback related to financial implications for hospitals, health care facilities, public health agencies, laboratories, blood banks, and other entities engaged in regional preparedness planning to implement and follow such guidelines, as applicable; and

''(4) consider financial requirements and potential incentives for entities to prepare for, and respond to, public health emergencies as part of the regional health care emergency preparedness and response system.

''(d) TECHNICAL ASSISTANCE.—The Assistant Secretary for Preparedness and Response, in consultation

with the Director of the Centers for Disease Control and Prevention and the Assistant Secretary of Labor for Occupational Safety and Health, may provide technical assistance and consultation towards meeting the guidelines described in subsection (b).

''(e) DEMONSTRATION PROJECT FOR REGIONAL HEALTH CARE PREPAREDNESS AND RESPONSE SYSTEMS.—

''(1) IN GENERAL.—The Assistant Secretary for Preparedness and Response may establish a demonstration project pursuant to the development and implementation of guidelines under subsection (b) to award grants to improve medical surge capacity for all hazards, build and integrate regional medical response capabilities, improve specialty care expertise for all-hazards response, and coordinate medical preparedness and response across State, local, tribal, territorial, and regional jurisdictions.

''(2) SUNSET.—The authority under this subsection shall expire on September 30, 2023.

''(f) GAO REPORT TO CONGRESS.—

''(1) REPORT.—Not later than 3 years after the date of enactment of this section, the Comptroller General of the United States (referred to in this subsection as the 'Comptroller General') shall submit

to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives a report on the extent to which hospitals and health care facilities have implemented the recommended guidelines under subsection (b), including an analysis and evaluation of any challenges hospitals or health care facilities experienced in implementing such guidelines.

''(2) CONTENT.—The Comptroller General shall include in the report under paragraph (1)—

''(A) data on the preparedness and response capabilities that have been informed by the guidelines under subsection (b) to improve regional emergency health care preparedness and response capability, including hospital and health care facility capacity and medical surge capabilities to prepare for, and respond to, public health emergencies; and

''(B) recommendations to reduce gaps in incentives for regional health partners, including hospitals and health care facilities, to improve capacity and medical surge capabilities to prepare for, and respond to, public health emer-

gencies, consistent with subsection (a), which may include consideration of facilities participating in programs under section 319C–2, programs under the Centers for Medicare & Medicaid Services (including innovative health care delivery and payment models), and input from private sector financial institutions.

''(3) CONSULTATION.—In carrying out paragraphs (1) and (2), the Comptroller General shall consult with the heads of appropriate Federal agencies, including—

''(A) the Assistant Secretary for Preparedness and Response;

''(B) the Director of the Centers for Disease Control and Prevention;

''(C) the Administrator of the Centers for Medicare & Medicaid Services;

''(D) the Assistant Secretary for Mental Health and Substance Use;

''(E) the Assistant Secretary of Labor for Occupational Safety and Health; and

''(F) the Secretary of Veterans Affairs.''.

SEC. 208. NATIONAL ACADEMY OF MEDICINE EVALUATION AND REPORT ON THE PREPAREDNESS OF HOSPITALS, LONG-TERM CARE FACILITIES, DIALYSIS CENTERS, AND OTHER MEDICAL FACILITIES FOR PUBLIC HEALTH EMERGENCIES.

(a) EVALUATION.—

(1) IN GENERAL.—As soon as possible, but not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall enter into an arrangement with the National Academy of Medicine or, if the National Academy declines to enter into such an arrangement, another appropriate entity under which the National Academy (or other appropriate entity) agrees to evaluate the preparedness of hospitals, long-term care facilities, dialysis centers, and other medical facilities nationwide for public health emergencies, including natural disasters.

(2) ARRAY OF EXPERTS.—The arrangement under paragraph (1) shall require the National Academy (or other appropriate entity) to engage an array of experts, including appropriate government experts, when conducting the evaluation under paragraph (1).

(3) SPECIFIC MATTERS EVALUATED.—The arrangement under paragraph (1) shall require the National Academy of Medicine (or other appropriate entity)—

(A) to catalogue, review, and evaluate the efficacy of current rules and regulations for hospitals, long-term care facilities, dialysis centers, and medical facilities regarding emergency preparedness planning;

(B) to identify and prioritize options to implement policies for hospitals, long-term care facilities, dialysis centers, and other medical facilities nationwide that address future threats;

(C) to review all Federal grant programs that affect the preparedness of hospitals, long-term care facilities, dialysis centers, or other medical facilities for public health emergencies and provide recommendations for improving such preparedness by—

(i) improving such existing Federal grant programs; or

(ii) creating new Federal grant programs;

(D) to review, identify, and recommend best practices for improving emergency pre-

paredness at hospitals, long-term care facilities, dialysis centers, and other medical facilities;

(E) to identify and recommend best sources and guidelines for alterative or emergency power systems, including renewable sources, battery storage, and generators; and

(F) to identify and recommend best practices and guidelines for emergency preparedness planning related to access to clean water at hospitals, long-term care facilities, dialysis centers, and other medical facilities.

(b) REPORT.—

(1) IN GENERAL.—The arrangement under subsection (a)(1) shall require the National Academy of Medicine (or other appropriate entity) to submit to the Secretary of Health and Human Services and the Congress, not later than 3 years after the date of enactment of this Act, a report on the results of the evaluation conducted pursuant to this section.

(2) CONTENTS.—The report under paragraph (1) shall—

(A) describe the findings and conclusions of the evaluation conducted pursuant to this section; and

(B) include a strategy for improving the preparedness of hospitals, long-term care facilities, dialysis centers, and other medical facilities nationwide for public health emergencies, including natural disasters.

SEC. 209. LIMITATION ON LIABILITY FOR VOLUNTEER HEALTH CARE PROFESSIONALS.

(a) IN GENERAL.—Title II of the Public Health Service Act is amended by inserting after section 224 (42 U.S.C. 233) the following new section:

"SEC. 224A. LIMITATION ON LIABILITY FOR VOLUNTEER HEALTH CARE PROFESSIONALS.

''(a) LIMITATION ON LIABILITY.—Except as provided in subsection (b), a health care professional serving, for purposes of responding to a disaster, as a volunteer shall not be liable under Federal or State law for any harm caused by an act or omission of the professional in the provision of health care services if the act or omission occurs—

''(1) during the period of the disaster;

''(2) in the State or States for which the disaster is declared;

''(3) while the health care professional is acting in the professional's capacity as a volunteer;

''(4) in the course of providing health care services that are within the scope of the license, registration, or certification of the volunteer, as defined by the State of licensure, registration, or certification; and

''(5) while the health care professional is acting in a good faith belief that the individual being provided such health care services is in need of such health care services.

''(b) EXCEPTIONS.—Subsection (a) does not apply with respect to harm caused by an act or omission of a health care professional in the provision of health care services as described in such subsection if—

''(1) the harm was caused by an act or omission constituting willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual harmed by the health care professional; or

''(2) the health care professional provided such health care services under the influence (as determined pursuant to applicable State law) of alcohol or an intoxicating drug.

''(c) PREEMPTION.—No State or political subdivision of a State may establish or continue in effect any laws relating to the liability for acts or omissions relating to

the provision of health care services by health care professionals serving, for purposes of responding to a disaster, as volunteers that are inconsistent with this section, unless such laws provide greater protection from such liability.

''(d) RELATIONSHIP TO VOLUNTEER PROTECTION ACT OF 1997.—The protections from liability under this section are in addition to the protections from liability under the Volunteer Protection Act of 1997.

''(e) DEFINITIONS.—In this section:

''(1) The term 'disaster' means—

''(A) a national emergency declared by the President under the National Emergencies Act;

''(B) an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act; or

''(C) a public health emergency that is determined by the Secretary under section 319 of this Act with respect to one or more States specified in such determination—

''(i) during only the initial period covered by such determination; and

''(ii) excluding any period covered by a renewal of such determination.

''(2) The term 'harm' includes physical, nonphysical, economic, and noneconomic losses.

''(3) The term 'health care professional' means an individual who is licensed, registered, or certified under Federal or State law to provide health care services.

''(4) The term 'health care services' means any services provided by a health care professional, or by any individual working under the supervision of a health care professional, that relate to—

''(A) the diagnosis, prevention, or treatment of any human disease or impairment; or

''(B) the assessment or care of the health of a human being.

''(5) The term 'State' includes each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

''(6)(A) The term 'volunteer' means a health care professional who, in providing health care services in response to a disaster, does not receive—

''(i) compensation; or

''(ii) any other thing of value in lieu of compensation, in excess of $500 per year.

''(B) For purposes of subparagraph (A), the term 'compensation'—

''(i) includes payment under any insurance policy or health plan, or under any Federal health care program (as defined in section 1128B(f) of the Social Security Act) or State health benefits program; and

''(ii) excludes—

''(I) reasonable reimbursement or allowance for expenses actually incurred;

''(II) receipt of paid leave; and

''(III) receipt of items to be used exclusively for providing the health care services referred to in subparagraph (A).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to claims for relief for which the act or omission giving rise to the claim occurred on or after the date that is 90 days after the date of the enactment of this Act.

(c) SENSE OF CONGRESS.—It is the sense of the Congress that—

(1) health care professionals should be encouraged to register with the Emergency System for Ad-

vance Registration of Volunteer Health Professionals (ESARVHP), and States should employ online registration with the promptest processing possible of such registrations to foster the rapid deployment and utilization of volunteer health care professionals following a disaster;

(2) Federal and State agencies and licensing boards should cooperate to facilitate the timely movement of properly licensed volunteer health care professionals to areas affected by a disaster; and

(3) the appropriate licensing entities should verify the licenses of volunteer health care professionals serving disaster victims as soon as is reasonably practical following a disaster.

TITLE III—ACCELERATING MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

SEC. 301. STRATEGIC NATIONAL STOCKPILE AND SECURITY COUNTERMEASURE PROCUREMENT.

(a) COORDINATION WITH THE ASPR.—Subsection (a)(1) of section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended by inserting ''the Assistant Secretary for Preparedness and Response and'' before

''the Director of the Centers for Disease Control and Prevention''.

(b) EVALUATION OF OBSTACLES TO RAPID DELIVERY OF MEDICAL COUNTERMEASURES.—Section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)) is amended by adding at the end the following:

''(4) RAPID DELIVERY STUDY.—The Assistant Secretary for Preparedness and Response may conduct a study on issues that have the potential to adversely affect the handling and rapid delivery of safe, secure, or sterile medical countermeasures to individuals who are at risk during public health emergencies occurring in the United States.

''(5) NOTICE TO CONGRESS.—Not later than 9 months after the date of the enactment of this paragraph, the Assistant Secretary for Preparedness and Response shall notify the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, whether or not the study authorized under paragraph (4) will be conducted.

''(6) REPORT TO CONGRESS.—If the Assistant Secretary for Preparedness and Response conducts the study authorized under paragraph (4), the Assistant Secretary, not later than 18 months after the

date on which such study is completed, shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate containing the findings of such study.''.

(c) CONGRESSIONAL NOTIFICATION OF MATERIAL THREAT DETERMINATION.—Section 319F–2(c)(2)(C) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(2)(C)) is amended by striking ''The Secretary and the Homeland Security Secretary shall promptly notify the appropriate committees of Congress'' and inserting ''The Secretary and the Secretary of Homeland Security shall send to Congress, on an annual basis, all current material threat determinations and shall promptly notify the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives that a determination has been made pursuant to subparagraph (A) or (B)''.

(d) AUTHORIZATION OF APPROPRIATIONS.—Section 319F–2(f)(1) of the Public Health Service Act (42 U.S.C. 247d–6b(f)(1)) is amended by striking ''$533,800,000 for each of fiscal years 2014 through 2018'' and inserting

''$610,000,000 for each of fiscal years 2019 through 2023, to remain available until expended''.

(e) BIOSHIELD SPECIAL RESERVE FUND.—Paragraph (1) of section 319F–2(g) of the Public Health Service Act (42 U.S.C. 247d–6b(g)) is amended to read as follows:

''(1) AUTHORIZATION OF APPROPRIATIONS.—In addition to amounts appropriated to the special reserve fund prior to the date of the enactment of this subsection, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section 319L (relating to the Biomedical Advanced Research and Development Authority), $7,100,000,000 for the fiscal years 2019 through 2028. Funds authorized by the preceding sentence for fiscal years 2020 through 2027 may be provided by advance appropriation, to be obligated at a rate of not less than $710,000,000 per year. Amounts appropriated pursuant to this paragraph are authorized to remain available until expended.''.

SEC. 302. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.

(a) UPDATING DEFINITION OF OTHER TRANSACTIONS.—Section 319L(a)(3) of the Public Health Serv-

ice Act (42 U.S.C. 247d–7e(a)(3)) is amended by striking '', such as the Secretary of Defense may enter into under section 2371 of title 10, United States Code''.

(b) PREPARING FOR PANDEMIC INFLUENZA, ANTIMICROBIAL RESISTANCE, AND OTHER SIGNIFICANT THREATS.—Section 319L(c)(4) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(4)) is amended by adding at the end the following:

''(F) STRATEGIC INITIATIVES.—The Secretary, acting through the Director of BARDA, may implement strategic initiatives, including by building on existing programs and by awarding grants supporting innovative candidate products in preclinical and clinical development, to address priority, naturally occurring and man-made threats that, as determined by the Secretary, pose a significant level of risk to national security based on the characteristics of a chemical, biological, radiological, or nuclear threat, or existing capabilities to respond to such a threat (including medical response and treatment capabilities and manufacturing infrastructure). Such initiatives shall accelerate and support the advanced research, development,

and procurement of, countermeasures and products, as applicable, to address areas including—

''(i) chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, for which insufficient approved, licensed, or authorized countermeasures exist, or for which such threat, or the result of an exposure to such threat, may become resistant to countermeasures or existing countermeasures may be rendered ineffective;

''(ii) threats that consistently exist or continually circulate and have significant potential to become a pandemic, such as pandemic influenza, which may include the advanced research and development, manufacturing, and appropriate stockpiling of qualified pandemic or epidemic products, and products, technologies, or processes to support the advanced research and development of such countermeasures (including multiuse platform technologies for diagnostics, vaccines, and therapeutics; virus seeds; clinical trial lots; novel virus

strains; and antigen and adjuvant material); and

''(iii) threats that may result primarily or secondarily from a chemical, biological, radiological, or nuclear agent, or emerging infectious disease, and which may present increased treatment complications such as the occurrence of resistance to available countermeasures or potential countermeasures, including antimicrobial resistant pathogens.''.

(c) TRANSACTION AUTHORITIES.—Section 319L(c)(5)(A) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(5)(A)) is amended—

(1) by amending clause (i) to read as follows:

''(i) IN GENERAL.—The Secretary shall have the authority to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects under this section.'';

(2) in clause (ii)—

(A) by amending subclause (I) to read as follows:

''(I) To the maximum extent practicable, competitive procedures

shall be used when entering into agreements to carry out projects under this section.''; and

(B) in subclause (II), by striking ''$20,000,000'' and inserting ''$100,000,000''.

(d) PANDEMIC INFLUENZA PROGRAM.—Section 319L of the Public Health Service Act (42 U.S.C. 247d–7e) is amended—

(1) by redesignating subsections (d) through (f) as subsections (f) through (h), respectively; and

(2) by inserting after subsection (c) the following new subsections:

''(d) PANDEMIC INFLUENZA PROGRAM.—The Secretary, acting through the Director of BARDA, shall establish and implement a program that—

''(1) supports advanced research and development activities for qualified pandemic or epidemic products (as defined in section 319F–3(i)), including by developing innovative technologies to enhance rapid response to threats relating to pandemic influenza;

''(2) ensures readiness to respond to pandemic influenza threats by supporting the development and manufacturing of influenza virus seeds, clinical trial lots, and stockpiles of novel influenza strains; and

''(3) sustains and replenishes pandemic stockpiles of bulk antigen and adjuvant material, including annually testing the potency and shelf-life potential of all existing pandemic stockpiles held by the Department of Health and Human Services.

''(e) EMERGING INFECTIOUS DISEASE PROGRAM.—The Secretary, acting through the Director of BARDA, shall establish and implement a program that supports advanced research and development activities for qualified pandemic or epidemic products, and manufacturing infrastructure, activities with respect to an emerging infectious disease.''.

(e) FUNDING.—Subsection (f) of section 319L of the Public Health Service Act (42 U.S.C. 247d–7e), as redesignated by subsection (b)(1), is amended—

(1) in paragraph (2)—

(A) by inserting ''(other than subsections (d) and (e))'' after ''purposes of this section''; and

(B) by striking ''$415,000,000 for each of fiscal years 2014 through 2018'' and inserting ''$536,700,000 for each of fiscal years 2019 through 2023''; and

(2) by adding at the end the following new paragraphs:

''(3) FUNDING FOR PANDEMIC INFLUENZA PROGRAM.—

''(A) IN GENERAL.—To carry out the purposes of subsection (d), there is authorized to be appropriated $250,000,000 for each of fiscal years 2019 through 2023, to remain available until expended.

''(B) SUPPLEMENT NOT SUPPLANT.—Any funds provided to the Secretary under this paragraph shall be used to supplement and not supplant any other Federal funds provided to carry out the purposes of subsection (d).

''(4) FUNDING FOR EMERGING INFECTIOUS DISEASE PROGRAM.—

''(A) IN GENERAL.—To carry out the purposes of subsection (e), there is authorized to be appropriated $250,000,000 for each of fiscal years 2019 through 2023, to remain available until expended.

''(B) SUPPLEMENT NOT SUPPLANT.—Any funds provided to the Secretary under this paragraph shall be used to supplement and not supplant any other Federal funds provided to carry out the purposes of subsection (e).''.

SEC. 303. REPORT ON THE DEVELOPMENT OF VACCINES TO PREVENT FUTURE EPIDEMICS.

Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report detailing the activities carried out by the Department of Health and Human Services to support the development of vaccines to prevent future epidemics, including work carried out through domestic and global public-private partnerships and other collaborations intended to spur the development of such vaccines. Such report shall include information related to the provision of any funding or technical assistance to such entities.

TITLE IV—MISCELLANEOUS PROVISIONS

SEC. 401. CYBERSECURITY.

(a) NATIONAL HEALTH SECURITY STRATEGY.—Section 2802(a) of the Public Health Service Act (42 U.S.C. 300hh–1(a)) is amended by adding at the end the following:

''(4) CYBERSECURITY THREATS.—In the next version of the National Health Security Strategy prepared after the date of the enactment of this paragraph, the National Health Security Strategy shall include a national strategy focused on address-

ing cybersecurity threats to the public health and health care system, including—

''(A) defining the functions, capabilities, and gaps in such system; and

''(B) identifying strategies to strengthen the preparedness and response of such system to cybersecurity threats and incidents, including with respect to continuity of care and risk mitigation to prevent harm to human health in case of a cybersecurity incident.''.

(b) COORDINATION OF PREPAREDNESS FOR AND RESPONSE TO ALL-HAZARDS PUBLIC HEALTH EMERGENCIES.—Section 2811(c) of the Public Health Service Act (42 U.S.C. 300hh–10), as amended by sections 101 and 301, is further amended—

(1) by redesignating paragraph (4) as paragraph (5); and

(2) by inserting after paragraph (3) the following:

''(4) have lead responsibility within the Department of Health and Human Services for coordinating preparedness, response, and recovery activities within the health care sector to provide continuity of care during a cybersecurity incident; and''.

SEC. 402. MISCELLANEOUS FDA AMENDMENTS.

(a) DRUG DEVELOPMENT TOOLS.—Section 507(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) is amended—

(1) by redesignating paragraph (3) as paragraph (4); and

(2) by inserting after paragraph (2) the following:

''(3) NATIONAL SECURITY LIMITATION.—In making information publicly available pursuant to paragraph (1), the Secretary—

''(A) shall not disclose information that would compromise national security; and

''(B) may make available summaries in lieu of data and evidence contained in qualification submissions.''.

(b) EMERGENCY USE INSTRUCTIONS.—Subparagraph (A) of section 564A(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a(e)(2)) is amended by striking ''subsection (a)(1)(C)(i)'' and inserting ''subsection (a)(1)(C)''.

(c) PRODUCTS HELD FOR EMERGENCY USE.—Section 564B(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3b) is amended—

(1) in subparagraph (B), by inserting a comma after ''505''; and

(2) in subparagraph (C), by inserting ''or section 564A'' before the period at the end.

(d) REGULATORY MANAGEMENT PLANS.—Section 565(f) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bbb–4(f)) is amended—

(1) by redesignating paragraphs (3) through (6) as paragraphs (4) through (7), respectively;

(2) by inserting after paragraph (2) the following:

''(3) PUBLICATION.—The Secretary shall make available on the internet website of the Food and Drug Administration information regarding regulatory management plans, including—

''(A) the process by which an applicant may submit a request for a regulatory management plan;

''(B) the timeframe by which the Secretary is required to respond to such request;

''(C) the information required for the submission of such request;

''(D) a description of the types of development milestones and performance targets that could be discussed and included in such plans; and

''(E) contact information for beginning the regulatory management plan process.'';

(3) in paragraph (6), as so redesignated, in the matter preceding subparagraph (A)—

(A) by striking ''paragraph (4)(A)'' and inserting ''paragraph (5)(A)''; and

(B) by striking ''paragraph (4)(B)'' and inserting ''paragraph (5)(B)''; and

(4) in paragraph (7)(A), as so redesignated, by striking ''paragraph (3)(A)'' and inserting ''paragraph (4)(A)''.

(e) ANIMAL RULE REPORT.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the application of the requirements under section 565(d) of the of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4(d)) (referred to in this section as the ''animal rule'') as a component of medical countermeasure advanced development under the Biomedical Advanced Research and Development Authority and regulatory review by the Food and Drug Administration. In conducting such study, the Comptroller General shall examine the following:

(A) The extent to which advanced development and review of a medical countermeasure

are coordinated between the Biomedical Advanced Research and Development Authority and the Food and Drug Administration, including activities to facilitate appropriate and efficient design of studies to support approval, licensure, and authorization under the animal rule, consistent with the recommendations in the animal rule guidance, issued pursuant to section 565(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360bbb–4(c)) and entitled ''Product Development Under the Animal Rule Guidance for Industry'' (issued in October 2015), to resolve discrepancies in the design of adequate and well-controlled efficacy studies conducted in animal models related to the provision of substantial evidence of effectiveness for the product approved, licensed, or authorized under the animal rule.

(B) The consistency of the application of the animal rule among and between review divisions within the Food and Drug Administration.

(C) The flexibilities pursuant to the animal rule to address variations in countermeasure development and review processes, including the

extent to which qualified animal models are adopted and used within the Food and Drug Administration in regulatory decisionmaking with respect to medical countermeasures.

(D) The extent to which the guidance issued under section 565(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360bbb–4(c)), entitled, ''Product Development Under the Animal Rule Guidance for Industry'' (issued in October 2015), has assisted in achieving the purposes described in subparagraphs (A), (B), and (C).

(2) CONSULTATIONS.—In conducting the study under paragraph (1), the Comptroller General of the United States shall consult with—

(A) the Federal agencies responsible for advancing, reviewing, and procuring medical countermeasures, including the Office of the Assistant Secretary for Preparedness and Response, the Biomedical Advanced Research and Development Authority, the Food and Drug Administration, and the Department of Defense;

(B) manufacturers involved in the research and development of medical countermeasures to

address biological, chemical, radiological, and nuclear threats; and

(C) other biodefense stakeholders, as applicable.

(3) REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study conducted under paragraph (1) and recommendations to improve the application and consistency of the requirements under subsections (c) and (d) of section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) to support and expedite the research and development of medical countermeasures, as applicable.

(4) PROTECTION OF NATIONAL SECURITY.—The Comptroller General of the United States shall conduct the study and issue the assessment and report under this subsection in a manner that does not compromise national security.

SEC. 403. MEDICAL COUNTERMEASURE MASTER FILES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 565A the following:

"SEC. 565B. MEDICAL COUNTERMEASURE MASTER FILES.

"(a) APPLICABILITY OF REFERENCE.—

"(1) IN GENERAL.—A person may submit data and information in a master file to the Secretary with the intent to reference, or to authorize, in writing, another person to reference, such data or information to support a medical countermeasure submission (including a supplement or amendment to any such submission), without requiring the master file holder to disclose the data and information to any such persons authorized to reference the master file. Such data and information shall be available for reference by the master file holder or a person authorized by the master file holder only in accordance with applicable privacy and confidentiality protocols and regulations.

"(2) LIMITATION.—Notwithstanding paragraph (1), a person may not reference, or authorize another person to reference, data or information to support a medical countermeasure submission to the extent such data or information is in the master file

for an application for conditional approval under section 571.

''(b) MEDICAL COUNTERMEASURE MASTER FILE CONTENT.—

''(1) IN GENERAL.—A medical countermeasure master file may include data and information to support—

''(A) the development of medical countermeasure submissions to support the approval, licensure, classification, clearance, conditional approval, or authorization of one or more security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products; and

''(B) the manufacture of security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products.

''(2) REQUIRED UPDATES.—The Secretary may require, as appropriate, that the master file holder ensure that the contents of such master file are updated during the time such master file is referenced for a medical countermeasure submission.

''(c) SPONSOR REFERENCE.—

''(1) IN GENERAL.—Each incorporation of data or information contained in a master file by ref-

erence shall describe the incorporated material in a manner in which the Secretary determines appropriate and that permits the review of such data or information without necessitating resubmission of such data or information. Master files shall be submitted in an electronic format in accordance with section 745A and as specified in applicable guidance.

''(2) REFERENCE BY A MASTER FILE HOLDER.—A master file holder that is the sponsor of a medical countermeasure submission shall notify the Secretary in writing of the intent to reference the medical countermeasure master file as a part of the submission.

''(3) REFERENCE BY AN AUTHORIZED PERSON.—A sponsor of a medical countermeasure submission may, where the Secretary determines appropriate, incorporate by reference all or part of the contents of a medical countermeasure master file, if the master file holder authorizes the incorporation in writing.

''(d) ACKNOWLEDGMENT OF MASTER FILE BY THE SECRETARY.—The Secretary shall provide the master file holder with a written notification indicating that the Secretary has reviewed and relied upon specified data or information within a master file and the purposes for which

such data or information was incorporated by reference if the Secretary has reviewed and relied upon such specified data or information to support the approval, classification, conditional approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product. The Secretary may rely upon the data and information within the medical countermeasure master file for which such written notification was provided in additional applications, as applicable and appropriate and upon the request of the master file holder so notified in writing or by an authorized person of such holder.

''(e) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to—

''(1) alter the authority of the Secretary to approve, license, classify, clear, conditionally approve, or authorize drugs, biological products, or devices pursuant to this Act or section 351 of the Public Health Service Act (as authorized prior to the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018), including the standards of evidence, and applicable conditions, for approval under the applicable Act; or

''(2) alter the authority of the Secretary under this Act or the Public Health Service Act to deter-

mine the types of data or information previously submitted by a sponsor or any other person that may be incorporated by reference in an application, request, or notification for a drug, biological product, or device submitted under section 505(i), 505(b), 505(j), 512(b)(1), 512(b)(2), 564, 571, 520(g), 515(c), 513(f)(2), or 510(k) of this Act, or subsection (a) or (k) of section 351 of the Public Health Service Act, including a supplement or amendment to any such submission, and the requirements associated with such reference.

''(f) DEFINITIONS.—In this section:

''(1) The term 'master file holder' means a person who submits data and information to the Secretary with the intent to reference or authorize to reference such data or information to support a medical countermeasure submission, as described in subsection (a)(1).

''(2) The term 'medical countermeasure submission' means an investigational new drug application under section 505(i), a new drug application under section 505(b), or an abbreviated new drug application under section 505(j) of this Act, a biological product license application under section 351(a) of the Public Health Service Act or a biosimilar biologi-

cal product license application under section 351(k) of the Public Health Service Act, a new animal drug application under section 512(b)(1) or abbreviated new animal drug application under section 512(b)(2), an application for conditional approval of a new animal drug under 571, an investigational device application under section 520(g), an application with respect to a device under section 515(c), a request for classification of a device under section 513(f)(2), a notification with respect to a device under section 510(k), or request for an emergency use authorization under section 564 to support—

''(A) the approval, licensure, classification, clearance, conditional approval, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product; or

''(B) a new indication to an approved security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

''(3) The terms 'qualified countermeasure', 'security countermeasure', and 'qualified pandemic or epidemic product' have the meanings given such terms in sections 319F–1, 319F–2, and 319F–3, respectively, of the Public Health Service Act.''.

(b) STAKEHOLDER INPUT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs and in consultation with the Assistant Secretary for Preparedness and Response, shall solicit input from stakeholders, including stakeholders developing security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products, and stakeholders developing technologies to assist in the development of such countermeasures with respect to how the Food and Drug Administration can advance the use of tools and technologies to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products, including through the reliance on cross-referenced data and information contained within master files and submissions previously submitted to the Secretary as set forth in section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) GUIDANCE.—Not later than 2 years after the after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall publish draft guidance about how reliance on cross-referenced data and information contained within master

files under section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), or submissions otherwise submitted to the Secretary may be used for specific tools or technologies (including platform technologies) that have the potential to support and accelerate the development or manufacture of security countermeasures, qualified countermeasures, qualified pandemic or epidemic products. The Secretary, acting through the Commissioner of Food and Drugs, shall publish the final guidance not later than 3 years after the enactment of this Act.

SEC. 404. FORMAL STRATEGY RELATING TO CHILDREN SEPARATED FROM PARENTS AND GUARDIANS AS A RESULT OF "ZERO TOLERANCE" POLICY.

Not later than 14 days after the date of the enactment of this Act, the Assistant Secretary for Preparedness and Response shall submit to the Committee on Energy and Commerce of the House of Representatives a formal strategy—

(1) to reunify with their parent or guardian each child who, as a result of the ''zero tolerance'' policy, was separated from their parent or guardian and placed into a facility funded by the Department of Health and Human Services; and

(2) to address deficiencies identified by the previous work of the Committee, which began in 2014, regarding the oversight of, and care for, unaccompanied alien children in the custody of the Department.

SEC. 405. BIOLOGICAL THREAT DETECTION.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.), as amended by section 104, is further amended by inserting after section 319D–1 of such Act, the following new section:

"SEC. 319D–2. BIOLOGICAL THREAT DETECTION.

''(a) EXCHANGE OF INFORMATION.—

''(1) IN GENERAL.—The Secretary of Health and Human Services, in coordination with the Secretary of Defense and the Secretary of Homeland Security, shall—

''(A) facilitate the identification by Federal departments and agencies of technological, operational, and programmatic successes and failures of domestic detection programs for intentionally introduced, accidentally released, and naturally occurring infectious diseases;

''(B) facilitate the exchange of information described in subparagraph (A) among Federal

departments and agencies that utilize biological threat detection technology; and

''(C) make recommendations on research, development, and procurement to Federal departments and agencies to replace and enhance biological threat detection systems in use, including recommendation for the transfer of biological threat detection technology among Federal departments and agencies.

''(2) CONSIDERATIONS.—In carrying out paragraph (1), the Secretary of Health and Human Services shall take into consideration the capabilities of the system with respect to each of the following:

''(A) Rapidly detecting, identifying, characterizing, and confirming the presence of biological threat agents.

''(B) Recovering live biological agents from collection devices.

''(C) Determining the geographical distribution of biological agents.

''(D) Determining the extent of environmental contamination and persistence of biological agents.

''(E) Providing advanced molecular diagnostics to State, local, tribal, and territorial

public health and other laboratories that support biological threat detection activities.

''(b) COLLABORATION.—The Secretary of Health and Human Services, in consultation with Secretary of Defense, the Secretary of Homeland Security, the Director of the Centers for Disease Control and Prevention, and the heads of other Federal departments and agencies that utilize biological threat detection technology, shall collaborate with State, local, tribal, and territorial public health laboratories and other users of current and future biological threat detection systems to develop—

''(1) biological threat detection requirements, including—

''(A) technical, quality, and biosafety standards, including the review of validation data prior to and throughout deployment of a biological threat detection system; and

''(B) requirements for—

''(i) the assessment of quality standards and the development and deployment of biological threat detection systems; and

''(ii) metrics for, collaborative assessment of, and deployment of biosafety standards;

''(2) a standardized integration strategy for—

''(A) the level to which biological threat detection processes and systems are defined and executed;

''(B) the locations at which such processes and systems are performed; and

''(C) the extent to which data is shared among State, local, tribal, and territorial public health laboratories and Federal departments and agencies;

''(3) State, local, tribal, and territorial laboratory training requirements for—

''(A) supporting and participating in biological threat detection systems; and

''(B) addressing flexibility at the jurisdictional level allowing for adoption of technology based on need and assessment of the efficacy and local utility of technology by the jurisdiction;

''(4) guidelines for a coordinated public health response addressing all aspects of a response, including clinical and epidemiological guidelines for utilizing information produced by biological threat detection systems and responding to intentionally introduced, accidentally released, and naturally occurring infectious diseases; and

''(5) a coordinated remediation plan with Federal departments and agencies and State and local public health agencies to facilitate rapid, safe, and coordinated restoration of facilities and localities after a contaminating biological event.''.

SEC. 406. STRENGTHENING MOSQUITO ABATEMENT FOR SAFETY AND HEALTH.

(a) REAUTHORIZATION OF MOSQUITO ABATEMENT FOR SAFETY AND HEALTH PROGRAM.—Section 317S of the Public Health Service Act (42 U.S.C. 247b–21) is amended—

(1) in subsection (a)(1)(B)—

(A) by inserting ''including programs to address emerging infectious mosquito-borne diseases,'' after ''subdivisions for control programs,''; and

(B) by inserting ''or improving existing control programs'' before the period at the end;

(2) in subsection (b)—

(A) in paragraph (1), by inserting '', including improvement,'' after ''operation'';

(B) in paragraph (2)—

(i) in subparagraph (A)—

(I) in clause (ii), by striking ''or'' at the end;

(II) in clause (iii), by striking the semicolon at the end and inserting ", including an emerging infectious mosquito-borne disease that presents a serious public health threat; or"; and

(III) by adding at the end the following:

"(iv) a public health emergency due to the incidence or prevalence of a mosquito-borne disease that presents a serious public health threat;"; and

(ii) by amending subparagraph (D) to read as follows:

"(D)(i) is located in a State that has received a grant under subsection (a); or

"(ii) demonstrates to the Secretary that the control program for which a grant is sought is consistent with existing State mosquito control plans or policies, and other applicable State preparedness plans.";

(C) in paragraph (4)(C), by striking "that extraordinary" and all that follows through the period at the end and inserting the following: "that—

''(i) extraordinary economic conditions in the political subdivision or consortium of political subdivisions involved justify the waiver; or

''(ii) the geographical area covered by a political subdivision or consortium for a grant under paragraph (1) has an extreme mosquito control need due to—

''(I) the size or density of the potentially impacted human population;

''(II) the size or density of a mosquito population that requires heightened control; or

''(III) the severity of the mosquito-borne disease, such that expected serious adverse health outcomes for the human population justify the waiver.''; and

(D) by amending paragraph (6) to read as follows:

''(6) NUMBER OF GRANTS.—A political subdivision or a consortium of political subdivisions may not receive more than one grant under paragraph (1).''; and

(3) in subsection (d), by striking ''Amounts appropriated under subsection (f)'' and inserting ''Amounts appropriated to carry out this section''.

(b) EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.—Section 2821 of the Public Health Service Act (42 U.S.C. 300hh–31) is amended—

(1) in subsection (a)(1), by inserting '', including mosquito and other vector-borne diseases,'' after ''infectious diseases''; and

(2) by amending subsection (b) to read as follows:

''(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $40,000,000 for each of fiscal years 2019 through 2023.''.

(c) GAO STUDY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the state of surveillance and control of mosquito-borne infectious diseases in the United States, including Indian country (as defined in section 1151 of title 18, United States Code) and territories, including the state of preparedness for conducting such surveillance and control. The study shall include—

(A) a description of the infrastructure and programs for mosquito control in the United

States (including Indian country (as so defined) and such territories), including—

(i) how such infrastructure and programs are organized and implemented at the Federal, State and local levels, including with respect to departments and agencies of the States, and local organizations (including special districts) involved in such control programs;

(ii) the role of the private sector in such activities;

(iii) how the authority for mosquito control impacts such activities; and

(iv) the funding sources for such infrastructure and programs, including Federal, State, and local funding sources;

(B) how mosquito-borne and other vector-borne disease surveillance and control is integrated into Federal, State, and local preparedness plans and actions, including how zoonotic surveillance is integrated into infectious disease surveillance to support real-time situational surveillance and awareness;

(C) Federal, State, and local laboratory capacity for emerging vector-borne diseases, in-

cluding mosquito-borne and other zoonotic diseases; and

(D) any regulatory challenges for developing and utilizing vector-control technologies and platforms as part of mosquito control strategies.

(2) CONSULTATIONS.—In conducting the study under paragraph (1), the Comptroller General of the United States shall consult with—

(A) State and local public health officials involved in mosquito and other vector-borne disease surveillance and control efforts;

(B) researchers and manufacturers of mosquito control products;

(C) stakeholders involved in mosquito abatement activities;

(D) infectious disease experts; and

(E) entomologists involved in mosquito-borne disease surveillance and control efforts.

(3) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy

and Commerce of the House of Representatives a report containing—

(A) the results of the study conducted under paragraph (1); and

(B) any relevant recommendations of the Comptroller General for preparedness and response efforts with respect to Zika virus and other mosquito-borne diseases.

SEC. 407. ADDITIONAL STRATEGIES FOR COMBATING ANTIBIOTIC RESISTANCE.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319E the following:

"SEC. 319E–1. ADVISORY COUNCIL ON COMBATING ANTIBIOTIC-RESISTANT BACTERIA.

''(a) DEFINITIONS.—In this section:

''(1) ACTION PLAN.—The term 'Action Plan' means the Action Plan described in section 319E(a)(1).

''(2) ADVISORY COUNCIL.—The term 'Advisory Council' means the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria established by Executive Order 13676 of September 18, 2014 (79 Fed. Reg. 56931; relating to combating antibiotic-resistant bacteria).

''(3) NATIONAL STRATEGY.—The term 'National Strategy' means the National Strategy for Combating Antibiotic-Resistant Bacteria issued by the White House in September 2014, and any subsequent update to such strategy or a successor strategy.

''(b) ADVISORY COUNCIL.—The Advisory Council shall provide advice, information, and recommendations to the Secretary regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676 of September 18, 2014 (79 Fed. Reg. 56931; relating to combating antibiotic-resistant bacteria), including the National Strategy, and the Action Plan.

''(c) MEETINGS AND DUTIES.—

''(1) MEETINGS.—The Advisory Council shall meet as the Chair determines appropriate but not less than twice per year, and, to the extent practicable, in conjunction with meetings of the task force described in section 319E.

''(2) RECOMMENDATIONS.—The Advisory Council shall make recommendations to the Secretary, in consultation with the Secretary of Agriculture and the Secretary of Defense, regarding programs and policies intended to—

''(A) preserve the effectiveness of antibiotics by optimizing their use;

''(B) advance research to develop improved methods for combating antibiotic resistance and conducting antimicrobial stewardship, as defined in section 319E(h)(3);

''(C) strengthen surveillance of antibiotic-resistant bacterial infections;

''(D) prevent the transmission of antibiotic-resistant bacterial infections;

''(E) advance the development of rapid point-of-care and agricultural diagnostics;

''(F) further research on new treatments for bacterial infections;

''(G) develop alternatives to antibiotics for animal health purposes;

''(H) maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal health care providers; and

''(I) improve international coordination of efforts to combat antibiotic resistance.

''(3) COORDINATION.—The Advisory Council shall, to the greatest extent practicable, coordinate activities carried out by the Council with the Anti-

microbial Resistance Task Force established under section 319E(a) (commonly referred to as the 'Combatting Antibiotic-Resistant Bacteria Task Force').''.

SEC. 408. ADDITIONAL PURPOSES FOR GRANTS FOR CERTAIN TRAUMA CENTERS.

Section 1241(a)(2) of the Public Health Service Act (42 U.S.C. 300d–41(a)(2)) is amended to read as follows:

''(2) to further the core missions of such trauma centers, including by addressing costs associated with patient stabilization and transfer, trauma education and outreach, coordination with local and regional trauma systems, essential personnel and other fixed costs, expenses associated with employee and nonemployee physician services, trauma staff recruitment and retention, ensuring surge capacity, trauma-related emotional and mental health services, and other investments needed to implement and maintain Regional Health Care Emergency Preparedness and Response Systems.''.

SEC. 409. REVIEW OF THE BENEFITS OF GENOMIC ENGINEERING TECHNOLOGIES AND THEIR POTENTIAL ROLE IN NATIONAL SECURITY.

(a) MEETING.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of

Health and Human Services (referred to in this section as the ''Secretary'') shall convene a meeting to discuss the potential role advancements in genomic engineering technologies (including genome editing technologies) may have in advancing national health security. Such meeting shall be held in a manner that does not compromise national security.

(2) ATTENDEES.—The attendees of the meeting under paragraph (1)—

(A) shall include—

(i) representatives from the Office of the Assistant Secretary for Preparedness and Response, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration; and

(ii) representatives from academic, private, and non-profit entities with expertise in genome engineering technologies, biopharmaceuticals, medicine, or biodefense, and other relevant stakeholders; and

(B) may include—

(i) other representatives from the Department of Health and Human Services,

as the Secretary determines appropriate; and

(ii) representatives from the Department of Homeland Security, the Department of Defense, the Department of Agriculture, and other departments, as the Secretary may request for the meeting.

(3) TOPICS.—The meeting under paragraph (1) shall include a discussion of—

(A) the current state of the science of genomic engineering technologies related to national health security, including—

(i) medical countermeasure development, including potential efficiencies in the development pathway and detection technologies; and

(ii) the international and domestic regulation of products utilizing genome editing technologies; and

(B) national security implications, including—

(i) capabilities of the United States to leverage genomic engineering technologies as a part of the medical countermeasure enterprise, including current applicable re-

search, development, and application efforts underway within the Department of Defense;

(ii) the potential for state and non-state actors to utilize genomic engineering technologies as a national health security threat; and

(iii) security measures to monitor and assess the potential threat of genomic engineering technologies and related technologies.

(b) REPORT.—Not later than 270 days after the meeting described in subsection (a) is held, the Assistant Secretary for Preparedness and Response shall issue a report to the congressional committees of jurisdiction on the topics discussed at such meeting, and provide recommendations, as applicable, to utilize innovations in genomic engineering (including genome editing) and related technologies as a part of preparedness and response activities to advance national health security. Such report shall be issued in a manner that does not compromise national security.

SEC. 410. CUT-GO OFFSET.

The total amount authorized to be appropriated to the Office of the Secretary of Health and Human Services

for each of fiscal years 2019 through 2023 is the amount that is $21,000,000 below the total amount appropriated to such Office for fiscal year 2018.